ORIGINAL

METHODIST HEALTHCARE MEMPHIS HOSPITALS

CN1602-009

TRAUGER & TUKE
ATTORNEYS AT LAW
THE SOUTHERN TURF BUILDING
222 FOURTH AVENUE NORTH
NASHVILLE, TENNESSEE 37219-2117
TELEPHONE (615) 256-8585
TELECOPIER (615) 256-7444

February 12, 2016

VIA HAND DELIVERY

Ms. Melanie Hill
Executive Director
Health Services & Development Agency
502 Deaderick Street, Ninth Floor
Nashville, Tennessee 37243

RE: Methodist Healthcare-Methodist Hospitals d/b/a
Methodist University Hospital Certificate of Need Application
For Onsite Replacement and Modernization of the Hospital Campus

Dear Ms. Hill:

Enclosed for filing please find the original and four (4) copies of the above-referenced certificate of need applications on behalf of my client Methodist Healthcare-Methodist Hospitals d/b/a Methodist University Hospital. Also enclosed is a check for the filing fee in amount of $45,000. Please date stamp two (2) copies of the certificate of need application and return them to me.

Thank you for your assistance.

Very truly yours,

Byron R. Trauger

Byron R. Trauger

BRT:kmn

Enclosures

cc: Carol Weidenhoffer

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF Shelby

Jeffrey H. Liebman, being first duly sworn, says that he/she is the applicant named in this application or his/her lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Tennessee Health Services and Development Agency and T.C.A. § 68-11-1601, *et seq.*, and that the responses to questions in this application or any other questions deemed appropriate by the Tennessee Health Services and Development Agency are true and complete.

Jeffrey H. Liebman CHIEF EXECUTIVE OFFICER

Signature/Title

Jeffrey H. Liebman
CEO, Methodist University Hospital
SVP, Methodist Healthcare

Sworn to and subscribed before me this the 10 day of February, 2016, a Notary Public in and for the County of Shelby, State of Tennessee.

NOTARY PUBLIC

My Commission expires 9/30/2017.

DEBRA D SAVAGE
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF SHELBY
MY COMM. EXP. SEPT. 30, 2017

HF-0056
Revised 7/02 - All forms prior to this date are obsolete

of the sale, or credit bid from a bank or other lending entity pre-approved by the successor trustee. The sale is free

Legal Notices

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that: Methodist Healthcare-Memphis Hospitals d/b/a Methodist University Hospital (a general hospital), owned and managed by Methodist Healthcare-Memphis Hospitals (a not for profit corporation), intends to file an application for a Certificate of Need for new construction and renovation of 470,000 SF of space at Methodist University Hospital, located at 1211-1265 Union Avenue, Memphis, TN 38104. The project is the onsite replacement and modernization of the campus including the construction of a new patient tower and adjacent building to consolidate ambulatory services. There is no change to the 617 licensed beds, yet 28 medical-surgical beds will be converted to critical care beds, and 204 beds will be relocated to the new patient tower. The project will add an Intraoperative MRI (IMRI), will add a third Linear Accelerator to existing Linear Accelerator services, and will relocate PET,CT and infusion equipment and services from 1588 Union Avenue. The project does not initiate or discontinue any other health service. The estimated project cost is $280,000,000.

The anticipated date of filing the application is on or before February 15, 2016. The contact person for this project is Carol Weidenhoffer, Senior Director of Planning, Research and Development, who may be reached at: Methodist Healthcare, 1407 Union Avenue, Suite 300, Memphis, TN, 38104, 901-516-0679.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street, Nashville, Tennessee 37243

Pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

Legal Notices

REQUEST FOR PROPOSAL
STATE OF TENNESSEE
State Building Commission Number: 529/000-06-2015
For
Value Added Reseller (VAR) Contracts

The Tennessee Department of General Services is requesting proposals to award multiple contracts to Value Added Resellers (VAR) to provide integrated lighting control systems, lighting fixture installation services, metering capability and other electrical work for the purpose of accomplishing energy savings projects for general government statewide, not limited to State facilities. Projects may include some or all of the following initiatives: lighting replacement or retrofit, LED lighting control, HVAC control system interface and installation, electrical motor and control upgrade, energy management systems and metering capabilities. The State intends to divide the awarded contracts by the Three Grand Divisions as pursuant to Tenn. Code Ann. Title 4, Chapter 1, Part 2. The VAR must be properly licensed in the State of Tennessee and must hold all necessary, appropriate business and professional license to provide service as required. The full text of the RFP for this project will be available at the STREAM website in *.PDF format requiring the *Acrobat Reader* utility. The RFP can be printed from this address:

http://tn.gov/generalservices/article/request-for-proposals

Proposers may request a copy of the RFP by contacting Nickie Smith, RFP Coordinator, at (615) 532-7475. Proposals are expected to be due in March 2016.

Lot 21, to the point of beginning, containing 0.361 acres or 15,740.12 square feet. Bearing are magnetic, taken September 3, 1996, James W. Crocker, TN RLS 1125, P.O. Box 923, Martin, TN 38237. Being the same property conveyed to Ryan S. Connor in Warranty Deed, as filed at Book D416, Page 392 in the Register's Office of Weakley County.

ALSO KNOWN AS: 200 Meadow Brook, Martin, TN 38237

This sale is subject to all matters shown on any applicable recorded plat; any unpaid taxes; any restrictive covenants, easements, or setback lines that may be applicable; any statutory rights of redemption of any governmental agency, state or federal; any prior liens or encumbrances as well as any priority created by a fixture filing; and to any matter that an accurate survey of the premises might disclose. In addition, the following parties may claim an interest in the above-referenced property:

RYAN S. CONNOR
MIDLAND FUNDING, LLC

The sale held pursuant to this Notice may be rescinded at the Successor Trustee's option at any time. The right is reserved to adjourn the day of the sale to another day, time, and place certain without further publication, upon announcement at the time and place for the sale set forth above. W&A No. 310052

DATED February 2, 2016
WILSON & ASSOCIATES
P.L.L.C.,
Successor-Trustee
1521 Merrill Drive, Suite D-220
Little Rock, Arkansas 72211
(501) 219-9388
W&A No.-310052
CA3T-
2/10/16
2/17/16
2/24/16
FOR SALE INFORMATION, VISIT WWW.MYFIR.COM and WWW.REALTYTRAC.COM

1. Name of Facility, Agency, or Institution

Methodist Healthcare-Memphis Hospitals d/b/a Methodist University Hospital
Name

1211 - 1265 Union Avenue
Address

Shelby
County

Memphis
City

TN
State

38104
Zip Code

2. Contact Person Available for Responses to Questions

Carol Weidenhoffer
Name

Corporate Director of Planning, Research and Development
Title

Methodist Le Bonheur Healthcare
Company Name

Carol.Weidenhoffer@mlh.org
E-mail address

1407 Union Avenue, Suite 300
Street or Route

Memphis
City

TN
State

38104
Zip Code

Employee
Association with Owner

901-516-0679
Phone Number

901-516-0621
Fax Number

3. Owner of the Facility, Agency or Institution See Attachment A:3

Methodist Healthcare – Memphis Hospitals
Name

901-516-0791
Phone Number

1211 Union Avenue, Suite 700
Street or Route

Shelby
County

Memphis
City

TN
State

38104
Zip Code

4. Type of Ownership of Control (Check One) See Attachment A:4

A.	Sole Proprietorship		F.	Governmental (State of TN or Political Subdivision)	
B.	Partnership		G.	Joint Venture	
C.	Limited Partnership		H.	Limited Liability Company	
D.	Corporation (For Profit)		I.	Other (Specify)	
E.	Corporation (Not-for-Profit)	X			

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

5. **Name of Management/Operating Entity (If Applicable)**

Not Applicable
Name

Street or Route

County

City

State

Zip Code

PUT ALL ATTACHMENTS AT THE END OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

6. **Legal Interest in the Site of the Institution** See Attachment A:6

A.	Ownership	X	D.	Option to Lease	
B.	Option to Purchase		E.	Other (Specify)	
C.	Lease of ____ Years				

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

7. **Type of Institution (Check as appropriate—more than one response may apply)**

A.	Hospital (Specify) Acute	X	I.	Nursing Home	
B.	Ambulatory Surgical Treatment Center (ASTC), Multi-Specialty		J.	Outpatient Diagnostic Center	
C.	ASTC, Single Specialty		K.	Recuperation Center	
D.	Home Health Agency		L.	Rehabilitation Facility	
E.	Hospice		M.	Residential Hospice	
F.	Mental Health Hospital		N.	Non-Residential Methadone Facility	
G.	Mental Health Residential Treatment Facility		O.	Birthing Center	
H.	Mental Retardation Institutional Habilitation Facility (ICF/MR)		P.	Other Outpatient Facility (Specify)	
			Q.	Other Specify	

8. **Purpose of Review (Check as appropriate—more than one response may apply)**

A.	New Institution		G.	Change in Bed Complement [Please note the type of change by underlining the appropriate response: Increase, Decrease, Designation, Distribution, Conversion, Relocation]	X
B.	Replacement/Existing Facility	X			
C.	Modification/Existing Facility	X			
D.	Initiation of Health Care Service as defined in TCA § 68-11-1607(4) (Specify)		H.	Change of Location	
E.	Discontinuance of OB Services		I.	Other (Specify)	
F.	Acquisition of Equipment LinAc/iMRI/ Hybrid OR	X			

9. **Bed Complement Data**

Please indicate current and proposed distribution and certification of facility beds.

		Current Licensed	Beds *CON	Staffed Beds	Beds Proposed	TOTAL Beds at Completion
A.	Medical	511		366	-28	483
B.	Surgical					
C.	Long-Term Care Hospital					
D.	Obstetrical					
E.	ICU/CCU	72		72	+28	100
F.	Neonatal					
G.	Pediatric					
H.	Adult Psychiatric	34		34		34
I.	Geriatric Psychiatric					
J.	Child/Adolescent Psychiatric					
K.	Rehabilitation					
L.	Nursing Facility (non-Medicaid Certified)					
M.	Nursing Facility Level 1 (Medicaid only)					
N.	Nursing Facility Level 2 (Medicare only)					
O.	Nursing Facility Level 2 (dually certified Medicaid/Medicare)					
P.	ICF/MR					
Q.	Adult Chemical Dependency					
R.	Child and Adolescent Chemical Dependency					
S.	Swing Beds					
T.	Mental Health Residential Treatment					
U.	Residential Hospice					
	TOTAL	**617**		**472**	**0**	**617**

*CON-Beds approved but not yet in service

10. **Medicare Provider Number** 44-0049
Certification Type Acute Care Facility

11. **Medicaid Provider Number** 44-0049
Certification Type Acute Care Facility

12. **If this is a new facility, will certification be sought for Medicare and/or Medicaid?**

The applicant, Methodist Healthcare–Memphis Hospitals, is a healthcare provider that operates five Shelby County hospitals under a single license. The system is certified for both Medicare and TennCare/Medicaid; and the system's acute care provider numbers cover all five hospitals--including Methodist University Hospital, which this application addresses.

13. **Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCO's/BHO's) operating in the proposed service area. Will this project involve the treatment of TennCare participants? If the response to this item is yes, please identify all MCO's/BHO's with which the applicant has contracted or plans to contract. Discuss any out-of-network relationships in place with MCO's/BHO's in the area.**

The Tennessee MCO's/BHO's operating in the project service area are United Healthcare offering United Healthcare Community Plan and Dual Complete (a Special Needs Plan), Blue Cross Blue Shield offering Blue Care and TennCare Select, and Wellpoint offering Amerigroup Community Care plan. The service area for this project also includes counties in North Mississippi and Eastern Arkansas, where Medicaid is available.

All of Methodist Healthcare's hospitals treat TennCare participants under the system's TennCare contracts. Methodist Healthcare–Memphis Hospitals contracts with United Healthcare, Blue Cross Blue Shield, Wellpoint, and Medicaid providers in adjoining States.

NOTE: **Section B** is intended to give the applicant an opportunity to describe the project and to discuss the need that the applicant sees for the project. **Section C** addresses how the project relates to the Certificate of Need criteria of Need, Economic Feasibility, and the Contribution to the Orderly Development of Health Care. **Discussions on how the application relates to the criteria should not take place in this section unless otherwise specified.**

SECTION B: PROJECT DESCRIPTION

Please answer all questions on 8 1/2" x 11" white paper, clearly typed and spaced, identified correctly and in the correct sequence. In answering, please type the question and the response. All exhibits and tables must be attached to the end of the application in correct sequence identifying the questions(s) to which they refer. If a particular question does not apply to your project, indicate "Not Applicable (NA)" after that question.

I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.

Proposed Services and Equipment

- This is an onsite replacement and modernization project on the campus of Methodist University Hospital, the flagship hospital for Methodist Healthcare – Memphis Hospitals.
- The proposed project consisting of 421,000 square feet (sf) of new space and 49,000 sf of renovated space is the execution of the master plan for Methodist University focusing on the relocation/consolidation of acute patient care services.
- A ten-story patient tower with an adjacent ambulatory building is proposed to consolidate currently disjointed clinical services, improve operational efficiencies by centralizing support services, and upgrade clinical space for high quality, patient-centered care.
- All acute care beds as well as imaging and surgical services currently housed in the oldest buildings on campus will be relocated to the new tower. Upon completion the new patient tower will house 204 of the 617 licensed beds, surgery, imaging, and pharmacy services, and feature consolidated, enhanced clinical centers of excellence for the West Cancer Center and Methodist University Hospital Transplant Institute.
- The project will convert twenty-eight medical-surgical beds to critical care beds.
- Another key element of the project is the consolidation of multiple, currently disjointed outpatient services into a newly constructed ambulatory building that will be situated to the south of the new tower for integrated access to the clinical space.
- The older, outdated buildings will be recycled and refurbished for patient education, resident education, support services, and administrative functions.
- Equipment needs for this project include the purchase of a new interoperable MRI (iMRI) for the surgical suite, a replacement Hybrid operating room system, and a third linear accelerator. The PET and CT in the West Cancer Center will be relocated from the Methodist operated West Clinic on Union Avenue – less than one mile away.
- The proposed project also includes the demolition of the Crews building at the corner of Union Avenue and Bellevue Boulevard which will improve circulation around the campus as well as increase the visibility of the main hospital entrance.
- Methodist plans to use Integrated Project Delivery (IPD) implementation on this project. It is a team approach with an agreement between the owner, contractor and architect for construction management. This innovative model reduces costs and waste through shared risks and rewards.
- Similar to recent construction project led by Methodist, the facility will be designed as a green building and upon completion the team will pursue Leadership in Energy and Environmental Design (LEED) certification by the U.S. Green Building Council. The design proposal seeks to reduce operating costs by using less energy and water as well as reduce the impacts on the environment.

Ownership Structure

- The applicant, Methodist Healthcare–Memphis Hospitals (Methodist), is a not-for-profit corporation that operates five Shelby County hospitals under a single license. The applicant is a wholly-owned subsidiary of a broader parent organization, Methodist Healthcare, which is a not-for-profit corporation with ownership and operating interests in healthcare facilities in West Tennessee and North Mississippi. Attachment A:4 contains an organization chart, and information on the facilities owned in whole or in part by Methodist Healthcare.

Service Area

- The project primary service area includes Shelby, Fayette and Tipton counties in Tennessee, DeSoto County in Mississippi, and Crittenden County in Arkansas. The secondary service area includes Tipton, Fayette, Lauderdale, Hardeman, Haywood, Dyer, and Madison Counties in Tennessee, Marshall, Tunica, Panola, Tate, and Coahoma Counties in Mississippi, and St. Francis, Mississippi, Poinsett, Lee, Phillips, and Craighead Counties in Arkansas. Please note the quaternary services of the hospital such as transplant serve a broader area attracting patients from around that nation.

Need

- As the system's tertiary academic medical center, Methodist University Hospital, located in the downtown medical center, is well positioned to serve the expansive tri-state service area. Through the partnership with the University of Tennessee Health Science Center, Methodist helps train the next generation of medical professionals and brings cutting-edge research and treatment to area patients. Methodist University is committed to education and advancements in clinical care and as such is a vital organization to Methodist Healthcare, the downtown medical district and broader tri-state area.
- Methodist University brings together research, medicine, and innovation to treat incredibly complex medical cases and advance the practice of medicine. The regional and national growth—and the continuance of this growth—of associated programs have created more of a need for intensive medical capacity and state-of-the-art facilities.
- Over the last three years, the hospital's critical care units have experienced increasingly high occupancy rates consistently exceeding 80%. The redistribution of medical-surgical beds to critical care will improve patient flow, wait times, and patient experience.
- The current campus is the product of decades of incremental expansion, with both inpatient and outpatient services interspersed and spread across a complex of buildings spanning six blocks and almost nineteen acres The campus needs restructuring, along with major renovation and modernization to meet twenty-first century standards. The older buildings on the campus – those built 1950-70 – pose serious challenges for today's clinical standards and state-of-the art technology. Conditions in the older buildings are not conducive to Methodist's trademark patient and family centered care.
- Methodist completed a comprehensive assessment of the campus infrastructure and updated the master plan to meet long term vision for the hospital and health system. The physical plant alone warrants the need for the project. The planning priorities for the project focus on consolidation, efficiency, organization, improvements/upgrades, flexibility, and recycling an aging infrastructure.
- Methodist believes an investment in the future of Methodist University Hospital required a critical review of all clinical program priorities, inpatient capacity, outpatient services, support services, and the result is this plan for campus modernization.

Existing Resources

- In the project's Tennessee primary service area, there are eleven adult acute care hospitals (including Methodist University) with a total of 3,844 licensed beds of which almost 80% were staffed (or 3,042 beds) in 2014. The average daily census for the market in 2014 was 2,704 (or 70% occupancy). There were 125,256 inpatient discharges and 716,500 inpatient days during this period.

Project Cost, Funding, Feasibility

- The project cost of $280,000,000 will be funded in cash by the applicant's parent, Methodist Healthcare. Methodist Healthcare is, and will remain, financially viable.

Staffing

- The project will not require the addition of FTEs.

II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.

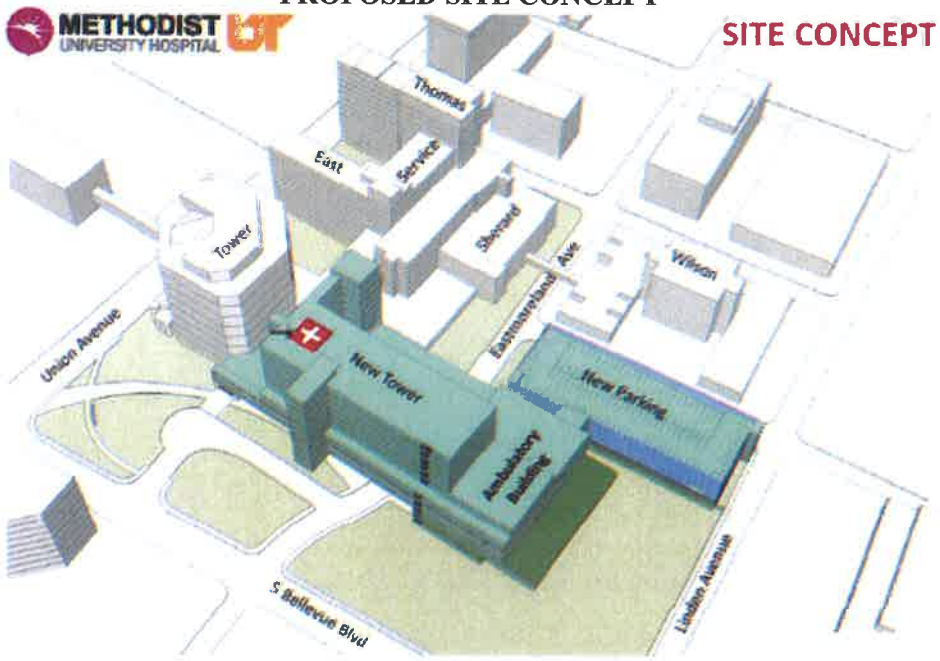
A. Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc.

1. Overview of the Project

This is an onsite replacement and modernization project on the campus of Methodist University Hospital, the flagship hospital for Methodist Healthcare–Memphis Hospitals. Over the nine months, Methodist completed a comprehensive assessment of the campus infrastructure and updated the Master Plan to meet the long term vision for the hospital and health system. The proposed project consisting of approximately 421,000 sf of new space and 49,000 sf of renovated space is the execution of the master plan for Methodist University focusing on the relocation/consolidation of acute patient care services.

The construction consists of a new ten-story patient tower which will be built on top of existing Emergency Department (ED) and span over Eastmoreland Avenue. The base of the new tower across Eastmoreland extends into an existing parking area and is referred to in the application as the ambulatory building – given that it will house many outpatient services. See Diagram 1 below for the site concept.

DIAGRAM 1
METHODIST UNIVERSITY CAMPUS
PROPOSED SITE CONCEPT



The proposed new patient tower will consolidate currently disjointed clinical services, improve operational efficiencies by centralizing support services, and upgrade clinical space for high quality, patient-centered care. All acute care beds (medical-surgical and critical care) as well as imaging and surgical services will relocate from the oldest buildings on campus (East, Service, and Thomas also noted on diagram 1 above) to the new tower. The older, outdated buildings will be recycled and refurbished for patient education, resident education, support services, and administrative functions.

Another key feature of the project is the consolidation of multiple outpatient centers spread across the existing campus. The base of the new tower –or the ambulatory building– on the south side of Eastmoreland Avenue will serve as the new entrance for imaging, ambulatory surgery, transplant clinic, and cancer clinic services with integrated access to the new clinical space.

The proposed project also includes the demolition of the Crews building at the corner of Union Avenue and Bellevue which will improve circulation around the campus as well as increase the visibility of the main hospital entrance. Old cooling towers on Union Avenue between the existing patient tower and the East building are also slated for demolition with this project to open greenspace.

An existing parking garage on Eastmoreland will also be demolished to accommodate new patient tower. A new larger parking garage (noted in diagram 1 above as new parking) will be constructed for expanded parking capabilities. The construction of a parking garage does not require Certificate of Need approval and these costs for demolition of the old garage and construction of the new garage are not included in this project.

The project will entail 421,000 sf of new space and 49,000 sf of renovated space. The estimated total project costs are $280,000,000.

If granted CON approval, the new tower and ambulatory building will be constructed and scheduled to open by January 2019 then renovations to back fill the older, existing buildings with support, administrative, and educational functions will be complete by May 2020. The projections in this application use calendar years 2019 and 2020 as the project's first two full years of operation given the inpatient and outpatient hospital services will be operational with the construction of the tower and ambulatory building. The applicant is requesting four years to complete this project.

2. Detailed Description of the Project

Changes in Bed Allocations

Table 1 below shows that the 617 total licensed beds operated by Methodist University will not change. Methodist plans to convert twenty-eight medical-surgical beds to critical care beds to meet the demands of the rising acuity and complexity of today's inpatients.

TABLE 1
METHODIST UNIVERSITY HOSPITAL
PROPOSED ACUTE CARE BED CHANGES

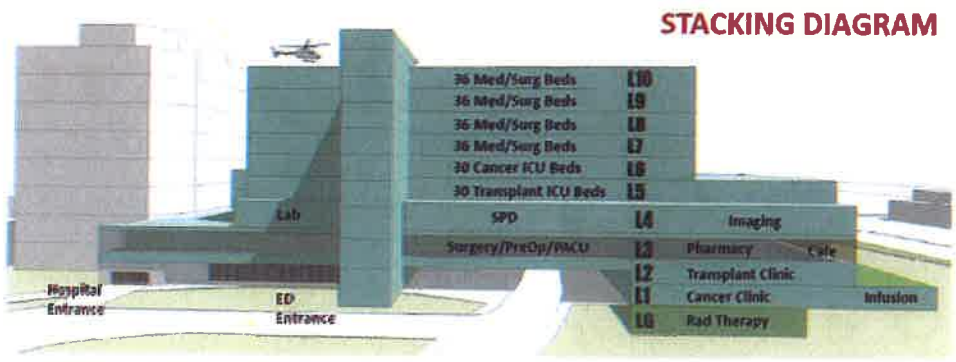
	Med-Surg	ICU/CCU	Psych	Total
Current Complement	511	80	34	617
Proposed Change	-28	+28	-	-
Proposed Complement	483	100	34	617

Square Footage Changes

The total square footage of the project is as follows; detailed data by department are shown on the Cost and Square Footage chart shown on pages 14. (The data excludes non-reviewable components of the campus such as existing medical office buildings and the planned parking garage.)

	Square Feet
Total Square Feet Renovated:	49,000
Total Square Feet New Construction:	421,000
Total Project Square Feet:	470,000
Total Square Feet to be Demolished:	129,408 (Crews)
Total Hospital Area, Before the Project:	1,366,697
Plus: New Construction	+ 421,000
Less: Demolition	- 129.408
Total Hospital Area, After the Project:	1,658,289

DIAGRAM 2
METHODIST UNIVERSITY CAMPUS
PROPOSED STACKING DIAGRAM



Please refer to Diagrams 2 for visual images of the proposed site plan and floor-by-floor summaries below.

Floor-by-Floor Summary of the Project
In the following narrative, "MUH Campus" refers to the existing hospital structure. The two new structures which will be constructed over the existing ED are the new ten-story tower and the ambulatory building located to the south of Eastmoreland. To keep it simple, the two new structures will be referred to as the "New Tower". Reference is also made to seven main sections of the MUH Campus, i.e., Crews, Tower, Link, East, Service, Sherard, and Thomas buildings. Floor plans and stacking diagrams are provided for easy reference.

Ground Level of the New Tower
As part of the goal for consolidation of outpatient cancer services, the ground level of the New Tower (located south of the existing ED and Eastmoreland) will house the radiation oncology therapy department. Radiation therapy currently is located in the basement level of the MUH Campus, Thomas building.

Level One of the New Tower
Level one (also located south of the existing ED and Eastmoreland) will consist of the remaining West Cancer Center outpatient services, to include the outpatient clinic, infusion center, and administrative support spaces. A dedicated entrance and patient drop-off for the cancer center will be provided with access from South Bellevue Boulevard. The existing infusion center is currently located off campus at the West Cancer Center at 1588 Union Avenue - less than a mile from the MUH Campus - which is and will be operated as a Methodist Memphis Hospitals hospital-based service.

Level Two of the New Tower
Level two will primarily consist of the consolidation of the Transplant Institute which will include the transplant outpatient clinic and Center for Advanced Liver Diseases (CALD). Collocated on this floor will be the dialysis clinic. These functions are currently located on level one of the Sherard building, but are currently not contiguous. A dedicated entrance and patient drop-off for the Transplant Institute will be provided with access from South Bellevue Boulevard.

Level Three of the New Tower
Level three will consist of the consolidated surgical department which will include the twenty operating rooms with supporting Post Anesthesia Care Unit (PACU) beds, and prep/recovery beds. The current surgical department is located on level three of the East and Service building. Also located on this level will be a consolidation of inpatient pharmacy services which are relocating from the ground level of Tower. Finally, a small café will be located on level three to provide additional amenities for outpatients, families, and visitors.

Level Four of the New Tower
Level four will consist of imaging services which are relocating from the Sherard building. The existing MRI suite located on the ground level of the Link building will be included in the relocation to the New Tower.

Level Five of the New Tower
This inpatient floor will contain 30 ICU beds for the Transplant Institute. Currently, the Transplant ICU is located on level seven of the East building.

Level Six of the New Tower
This inpatient floor will contain 30 ICU beds for Cancer Center patients and other critical care patients.

Level Seven – Ten of the New Tower
This inpatient floor will contain 36 medical-surgical beds each relocated from East, Sherard, and Thomas.

Roof of the New Tower
The helipad is currently on the roof of the ED. The new tower will be constructed on top of the existing ED, so the helipad will be relocated to the roof of the new patient tower.

See Attachments B:III (A) and B:IV for the Plot Plans and Floor Plans.

3. Project Costs and Funding Sources

Project Costs
The total cost of the project for CON purposes is $280,000,000 which includes construction costs of $197,145,000 (including $6,750,000 site prep and $18,245,000 contingency costs). The project costs will be funded by cash contributions from Methodist Healthcare, the parent company of the applicant.

Applicants with hospital projects (construction cost in excess of $5 million) and other facility projects (construction cost in excess of $2 million) should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.

Please also discuss and justify the cost per square foot for this project.

Total construction costs excluding site prep and construction contingency are $172,150,000 (or $366 PSF) with new construction costs of $166,692,019 (or $396 PSF) and renovation costs of $5,457,981 (or $111 PSF).

The costs of the project are higher than average due to the scope of the project yet reasonable as compared to similar renovations done throughout Methodist Healthcare over the last few years and on recently approved CON's.

TABLE 2
COST PER SQUARE FOOT COMPARISON WITH APPROVED PROJECTS

CON Name	Date Filed	Cost per Square Foot
Methodist South Hospital Renovate and Expand Emergency Department	**Mar-15**	**$ 209**
Methodist Memphis Hospital Establish West Cancer Center	**Nov-13**	**$ 145**
Le Bonheur Children's Hospital Establish Pediatric Outpatient Center	**Nov-13**	**$ 152**
Campbell Clinic Surgery Center Construction & Renovation	**Aug-12**	**$ 244**
The Regional Medical Center – The Med Hospital Construction & Renovation	**Aug-12**	**$ 225**
Baptist Memorial Women's Hospital ED Construction & Renovation	**Dec-12**	**$ 238**

Total construction costs are also higher when compared to the HSDA construction costs ranges. Renovation costs for the project are at the first quartile, yet new construction costs are above the third quartile. Please note that three years of escalation are costs built into the construction estimates given the project timeline which equate to roughly $50 PSF. Other factors that increase the costs projections for this project are:

- the new patient tower spans an active road
- the new patient tower will connect to existing facilities at several locations
- the site is not a greenfield site yet is an onsite modernization project in a busy campus

See the cost per square foot comparisons below.

TABLE 3
HOSPITAL CONSTRUCTION COST PER SQUARE FOOT
YEARS: 2012-2014

	Renovated Construction	New Construction	Total Construction
1st Quartile	$110.98/sq ft	$224.09/sq ft	$156.78/sq ft
Median	$192.46/sq ft	$259.66/sq ft	$227.88/sq ft
3rd Quartile	$297.82/sq ft	$296.52/sq ft	$298.66/sq ft

Source: CON approved applications for years 2012 through 2014

If the project involves none of the above, describe the development of the proposal.

Not Applicable.

B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.

The proposed changes in bed complement at Methodist University Hospital are described in detail in the Section B.II.A narrative immediately preceding this section. This redistribution from medical-surgical beds to intensive care beds will not add beds to the hospital or service area; it will not change the license of the applicant.

Methodist University is the core teaching hospital for University of Tennessee Health Science Center (UTHSC). The hospital's academic focus offers highly specialized services for complex diseases, illnesses, and injuries, develops technology, and carries out research to improve lives. The regional and national

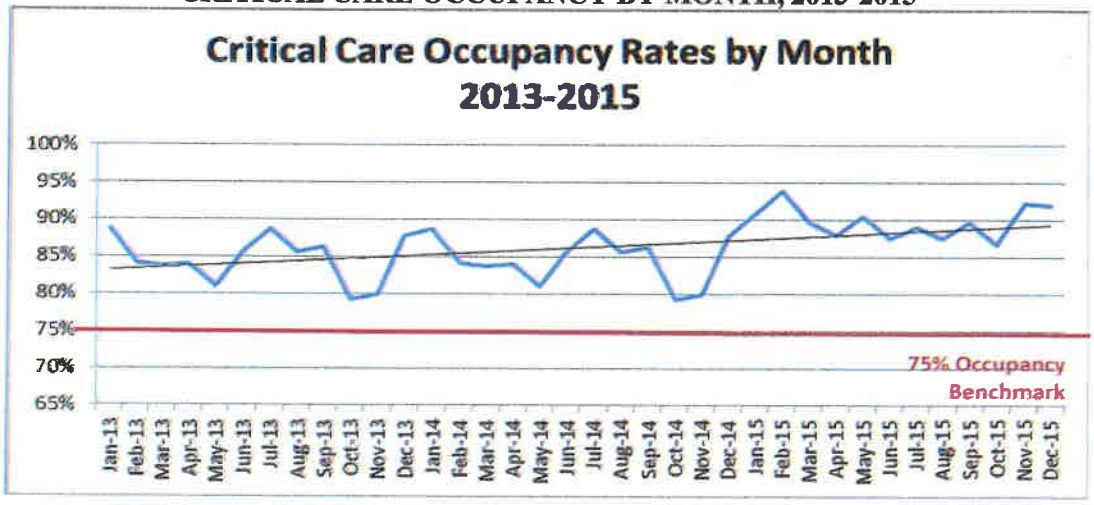
outreach of the academic programs is shifting the need for more intensive medical capacity and need for a state-of-the-art facility.

To remedy the Methodist plans to convert twenty-eight medical-surgical beds to critical care beds in the new patient tower. Over the last three years, the hospital's intensive care units have experienced increasingly high occupancy rates consistently exceeding 80%. This redistribution will improve patient flow, wait times, and patient experience with the addition of intensive care beds.

METHODIST UNIVERSITY HOSPITAL
CRITICAL CARE OCCUPANCY BY YEAR, 2013-2015

	2013	2014	2015
ICU Beds	72	72	72
Patient Days	22,212	22,797	23,570
Average Daily Census	60.9	62.5	64.6
Occupancy Rate	84.5%	86.7%	89.7%

METHODIST UNIVERSITY
CRITICAL CARE OCCUPANCY BY MONTH, 2013-2015



Square Footage Cost Per Square Footage Chart

A. Unit / Department	Existing Location	Existing SF	Temporary Location	Proposed Final Location	Proposed Final Square Footage			Proposed Final Cost/ SF		
					Renovated	New	Total	Renovated	New	Total
GROUND FLOOR										
Radiation Therapy	Thomas Basement	13,701 SF		Ground New Tower		19,500 SF	19,500 SF		$588 /sf	$ 11,462,959
1ST FLOOR										
Oncology Infusion Center	Offsite			1st New Tower		23,622 SF	23,622 SF		$344 /sf	$ 8,128,323
Oncology Center Clinics	Offsite			1st New Tower		23,622 SF	23,622 SF		$312 /sf	$ 7,366,418
Dock				1st New Tower		1,000 SF	1,000 SF		$254 /sf	$ 254,496
2ND FLOOR										
Transplant Clinic	1st Sherard	19,432 SF		2nd New Tower		31,007 SF	31,007 SF		$312 /sf	$ 9,669,398
Dialysis	1st Sherard	5,084 SF		2nd New Tower		4,800 SF	4,800 SF		$290 /sf	$ 1,393,601
3RD FLOOR										
Surgery	1st & 3rd Service	52,746 SF		3rd New Tower		78,266 SF	78,266 SF		$520 /sf	$ 40,678,185
Pharmacy	Ground Tower	9,202 SF		3rd New Tower		9,000 SF	9,000 SF		$366 /sf	$ 3,290,506
Café				3rd New Tower		2,000 SF	2,000 SF		$294 /sf	$ 587,853
4TH FLOOR										
Laboratory				4th New Tower		1,183 SF	1,183 SF		$484 /sf	$ 572,115
Sterile Processing Department (shell)				4th New Tower		20,000 SF	20,000 SF		$201 /sf	$ 4,014,591
Diagnostic Imaging	4th Sherard and Ground Link	22,975 SF		4th New Tower		21,000 SF	21,000 SF		$473 /sf	$ 9,936,027
5TH FLOOR										
30-Bed ICU	7th East	8,057 SF		5th New Tower		31,000 SF	31,000 SF		$401 /sf	$ 12,445,231
6TH FLOOR										
30-Bed ICU	2nd Sherard	17,360 SF		6th New Tower		31,000 SF	31,000 SF		$401 /sf	$ 12,445,231
7TH - 10TH FLOORS										
36-Bed Med/Surg	Various	110,796 SF		7th-10th New Tower		124,000 SF	124,000 SF		$358 /sf	$ 44,447,086
RENOVATIONS										
Behavioral Health	8th Crews	14,895 SF		Thomas	22,000 SF		22,000 SF	$89 /sf		$ 1,965,908
Laboratory	6th Sherard	16,500 SF		Sherard	16,500 SF		16,500 SF	$189 /sf		$ 3,124,573
Support				Thomas	10,500 SF		10,500 SF	$35 /sf		$ 367,500
SUBTOTAL CONSTRUCTION					**49,000 SF**	**421,000 SF**	**470,000 SF**	**$111.39 /sf**	**$395.94 /sf**	**$172,150,000**
DEMOLITION										$1,900,000
SITEWORK										$4,850,000
SUBTOTAL SITE PREP										**$6,750,000**
TOTAL CONSTRUCTION AND SITE PREP										**$178,900,000**

C. As the applicant, describe your need to provide the following health care services (if applicable to this application): The applicant is approved for Radiation Therapy/Linear Accelerator, Magnetic Resonance Imaging (MRI), and Positron Emission Tomography (PET) services and equipment already. The PET equipment will be relocated to this site, and the Linear Accelerator and iMRI are requests for additional units for existing services at this location.

1. **Adult Psychiatric Services**
2. **Alcohol and Drug Treatment for Adolescents (exceeding 28 days)**
3. **Birthing Center**
4. **Burn Units**
5. **Cardiac Catheterization Services**
6. **Child and Adolescent Psychiatric Services**
7. **Extracorporeal Lithotripsy**
8. **Home Health Services**
9. **Hospice Services**
10. **Residential Hospice**
11. **ICF/MR Services**
12. **Long-term Care Services**
13. **Magnetic Resonance Imaging (MRI)**
14. **Mental Health Residential Treatment**
15. **Neonatal Intensive Care Unit**
16. **Non-Residential Methadone Treatment Centers**
17. **Open Heart Surgery**
18. **Positron Emission Tomography**
19. **Radiation Therapy/Linear Accelerator**
20. **Rehabilitation Services**
21. **Swing Beds**

D. Describe the need to change location or replace an existing facility.

See the response to Section C under the responses to the Project-Specific Review Criteria: Construction, Renovation, Expansion, and Replacement of Health Care Institutions.

E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of $1.5 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:

The Linear Accelerator, iMRI, and Hybrid Operating Room (OR) system proposed purchases are fixed units therefore #2 below is not applicable. The Hybrid OR system is a replacement of existing equipment. Neither #1 nor #2 is applicable for the PET since the unit is being relocated and is not a new purchase.

1. **For fixed-site major medical equipment (not replacing existing equipment):**
   a. **Describe the new equipment, including:**
      1. **Total cost ;(As defined by Agency Rule).**

Equipment Type	Equipment	Maintenance (4 years)	Total Cost
iMRI	$ 3,959,767	$ 705,180	$ 4,664,947
Linear Accelerator	$ 2,636,000	$ 760,581	$ 3,396,581
Hybrid Operating Room	$ 1,972,443	$ 375,300	$ 2,347,743

2. **Expected useful life of all major moveable equipment is 7 years**

3. **List of clinical applications to be provided;**

LINEAR ACCELERATOR

"A linear accelerator (LINAC) is latest in radiation technology used for external beam radiation treatments for patients with cancer. The linear accelerator is used to treat all parts/organs of the body. It delivers high-energy x-rays to the region of the patient's tumor. These x-ray treatments can be designed in such a way that they destroy the cancer cells while sparing the surrounding normal tissue. The LINAC is used to treat all body sites, using conventional techniques, Intensity-Modulated Radiation Therapy (IMRT), Image Guided Radiation Therapy (IGRT) Stereotactic Radiosurgery (SRS) and Stereotactic Body Radio Therapy (SBRT)." *(source:* http://www.radiologyinfo.org/en/info.cfm?pg=linac*)*.

The equipment is optimized for both radiotherapy and radiosurgery and can treat cancers almost anywhere in the body, including lung, breast, abdomen and head and neck cancers.

iMRI

"Magnetic resonance imaging (MRI) is a noninvasive medical test that physicians use to diagnose and treat medical conditions. MRI uses a powerful magnetic field, radio frequency pulses and a computer to produce detailed pictures of organs, soft tissues, bone and virtually all other internal body structures. MRI does not use ionizing radiation (x-rays). Detailed MR images allow physicians to evaluate various parts of the body and determine the presence of certain diseases. The images can then be examined on a computer monitor, transmitted electronically, printed or copied to a CD."
http://www.radiologyinfo.org/en/info.cfm?pg=bodymr

An intraoperative magnetic resonance imaging (iMRI) unit is used in the neurosurgery operating room. This equipment will be used to assist neurosurgeons in epilepsy surgeries and the resection of brain tumors. Without this technology, MRI testing must be done in the hospital's radiology department post-operatively. This delayed imaging could identify the further need for surgery and the patient will have to undergo a subsequent surgery. iMRI is bridges the specialties of surgery and radiology. With this technology, the precision and success of surgical treatment increase.

HYBRID OR SYSTEM

"A hybrid operating room is an OR equipped with a large fixed imaging system that supports high-quality interventional imaging and complex open and minimally invasive surgeries. A revolutionary alternative to conventional operating rooms, the hybrid OR allows physicians to perform procedures using real-time image guidance, and to assess effectiveness and manage perioperative complications, all in a single encounter." *source: ECRI Institute*

Hybrid operating rooms are currently used mainly in cardiac, vascular and neuro-surgery, but could be suitable for a number of other surgical disciplines.

4. **Documentation of FDA approval.**

Please see Attachment B II (E)(4) FDA approvals

b. Provide current and proposed schedules of operations.

LINAC 7:30a – 4:30p Monday-Friday
iMRI and Hybrid OR system same as perioperative suite 7:00a – 5:00 p Monday-Friday

2. **For mobile major medical equipment:** Not Applicable
   a. **List all sites that will be served;**
   b. **Provide current and/or proposed schedule of operations;**
   c. **Provide the lease or contract cost.**
   d. **Provide the fair market value of the equipment; and**
   e. **List the owner for the equipment.**

3. **Indicate applicant's legal interest in equipment (*i.e.*, purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.**

   Methodist proposes to purchase all major moveable equipment included in this project. See Attachment B:II (E)(3) for the quotes from the vendors.

III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which must include:

See Attachment B:III (A) for the plot plan.

1. **Size of site (*in acres*);**
2. **Location of structure on the site; and**
3. **Location of the proposed construction.**
4. **Names of streets, roads or highway that cross or border the site.**

Please note that the drawings do not need to be drawn to scale. Plot plans are required for all projects.

(B) Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

Methodist University Hospital is in the heart of the Memphis Medical Center. The hospital campus is located on Union Avenue, in downtown Memphis, within a few blocks of the Union Avenue exit from Interstate-240 (I-240) which makes it easily accessible for area patients via automobile and ambulance. Union Avenue runs east-west from the Mississippi River (in downtown Memphis) to Houston-Levee Road in Germantown, Tennessee (changing names to Walnut Grove as it runs through the city). I-240 loops around the city of Memphis with major junctions at I-40 (east-west highway that traverses the state of Tennessee and locally connects Arkansas and Tennessee), I-55 (north-south highway locally connecting Tennessee to Mississippi, northern Arkansas and Missouri), and State Route 385 (loops through East Memphis suburbs) as well as several US Highways including US-64/US-70/US-79, US-78 and US-72.

The Memphis Area Transit Authority (MATA) services this area with Route 34, which lists Methodist University Hospital as a major stop on the route. Please see Attachment B: III (B) for a copy of this public transportation route.

IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an 8 1/2" x 11" sheet of white paper.

NOTE: *DO NOT SUBMIT BLUEPRINTS*. Simple line drawings should be submitted and need not be drawn to scale.

See Attachment B:IV. for the floor plans.

V. For a Home Health Agency or Hospice, identify: Not applicable.

1. **Existing service area by County;**
2. **Proposed service area by County;**
3. **A parent or primary service provider;**
4. **Existing branches; and**
5. **Proposed branches.**

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with Tennessee Code Annotated § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care." The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan (Guidelines for Growth), developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. *Please type each question and its response on an 8 1/2" x 11" white paper*. All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate "Not Applicable (NA)."

QUESTIONS

NEED

1. **Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth.**

   The applicant's mission embodies the spirit of the Guidelines for Growth and the Five Principles to Achieve Better Health as outlined in the State Health Plan. Methodist Le Bonheur Healthcare's mission is to partner with its medical staffs and collaborate with its patients and families to be the leader in high quality, cost effective healthcare in all sectors of its service area. Its geographical distribution makes Methodist Healthcare the area provider with the largest number of entry points, and the most socio-economically diverse patient population. This project complies with the mission and the tenants of the State Health Plan and Guidelines for Growth.

   Healthy Lives:
   The purpose of the State Health Plan is to improve the health of Tennesseans.

   Every person's health is the result of the interaction of individual behaviors, society, the environment, economic factors, and our genetic endowment. The State Health Plan serves to facilitate the collaboration of organizations and their ideas to help address health at these many levels.

   This project will reshape Methodist University in a manner that contributes to the Health Lives principle by improving both access to health services and the quality of health services. A key component of this is that Methodist University will be better positioned to start care coordination further upstream in the care continuum, which will go a long ways toward combating the effects of the determinants of health described by the Healthy Lives Principle.

   Access to Care:
   Every citizen should have reasonable access to health care.
   Many elements impact one's access to health care, including existing health status, employment, income, geography, and culture. The State Health Plan can provide standards for reasonable access, offer policy direction to improve access, and serve a coordinating role to expand health care access.

   Methodist Healthcare has strategically placed and maintained hospitals and ambulatory facilities in all quadrants of Shelby County as part of its mission. University Hospital remained committed to the inner city and mission markets even as competitors and other healthcare resources followed the population shift to the east. The hospital is centrally located in the downtown Memphis Medical Center making it easily

accessible patients and families in the tristate area. In keeping with the mission, access to healthcare services is not restricted by existing health status, employment, income, geography, or culture.

Barriers to accessing health services lead to unmet health needs, delays in receiving appropriate care, an inability to get preventive services, and preventable hospitalizations. The project will remove physical barriers, enhance aesthetic elements, and promote operational efficiencies to greatly improve patients' access to high-quality and patient-centered tertiary and ambulatory services.

Economic Efficiencies:

The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the continued development of the state's health care system.

The State Health Plan should work to identify opportunities to improve the efficiency of the state's health care system and to encourage innovation and competition.

The newly designed campus will improve access to and the efficiency of health care services offered by Methodist University. Improved access to ambulatory services, particularly preventive services, will allow patients to enter the care continuum further upstream, at a more cost-effective and efficient point of care. From a health system perspective, the campus will be designed in a way that supports evidence-based practices and minimized unnecessary variation.

Quality of Care:

Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.

Health care providers are held to certain professional standards by the state's licensure system. Many health care stakeholders are working to improve their quality of care through adoption of best practices and data-driven evaluation.

Patient safety and quality are central areas of focus in Methodist hospitals. The framework for Methodist Healthcare's approach to systematic quality improvement includes the following dimensions: safe, timely, effective, efficient, equitable, patient-centered, accessible and sustainable. The current design of the Methodist University campus poses certain challenges. This project will improve upon all of the above-mentioned dimensions. The clinical staff will have more opportunity for collaboration across modalities and with physicians for improved quality care. The more efficient flow in the proposed facility has fewer touch points, facilitates improved communication and consolidates work zones for more efficient and timely care.

Methodist has adopted a patient and family centered culture. Associates are encouraged to truly partner with patients and families, not only to involve them in decisions about care, but also gain the benefit of their insights to better plan and deliver care. The core principles for culture are respect and dignity, information sharing, participation and collaboration. The improved hospital design coupled with employment of these principles, patients can achieve better outcomes, and the hospital can improve the care for patients

Health Care Workforce:

The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.

The state should consider developing a comprehensive approach to ensure the existence of a sufficient, qualified health care workforce, taking into account issues regarding the number of providers at all levels and in all specialty and focus areas, the number of professionals in teaching positions, the capacity of medical, nursing, allied health and other educational institutions, state and federal laws and regulations impacting capacity programs, and funding.

Methodist University Hospital is the largest, most comprehensive hospital in the Methodist Healthcare system. It is a 617-bed facility located in the heart of the Memphis Medical Center.

As the major academic campus and principal teaching hospital of the UTHSC, it brings together research, medicine and innovation. This partnership supports multidisciplinary collaboration among doctors and clinical team members, leading to more advanced medical care for our patients.

Methodist University currently houses the latest technologies for diagnosis and treatment, including several centers that are unique in the Mid-South: Brain and Spine Institute, Transplant Institute, Head and Neck Surgery Center, Cardiovascular Institute, cancer services (in partnership with West Cancer Center), Methodist University Radiation Oncology Center, and thoracic surgery. All of which allow for an expansion of providers at many levels and with many specialties, people in teaching positions, and creates capacity for medical, nursing, allied health, and educational institutions. This project will also leverage the academic affiliation and support the development, recruitment, and retention of a quality workforce.

a. Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9) here.

Project-Specific Review Criteria: Construction, Renovation, Expansion, and Replacement of Health Care Institutions

1. **Any project that includes the addition of beds, services, or medical equipment will be reviewed under the standards for those specific activities.**

   Not applicable; no beds or services are being added to the applicant's licensed organization. The linear accelerator for this project is additional equipment for the existing Radiation Therapy program that has two linear accelerators currently. The iMRI is additional equipment for existing imaging program. The Hybrid OR system is a replacement for an existing unit. The PET for this project is the relocation of services and those criteria are included.

2. **For relocation or replacement of an existing licensed healthcare institution:**

   Not applicable. This project is not a full replacement or relocation project

   a. **The applicant should provide plans, which include costs for both renovation and relocation, demonstrating the strengths and weaknesses of each alternative.**

   b. **The applicant should demonstrate that there is acceptable existing and projected future demand for the proposed project.**

3. **For renovation or expansions of an existing licensed healthcare institution:**

   a. **The applicant should demonstrate that there is an acceptable existing demand for the proposed project.**

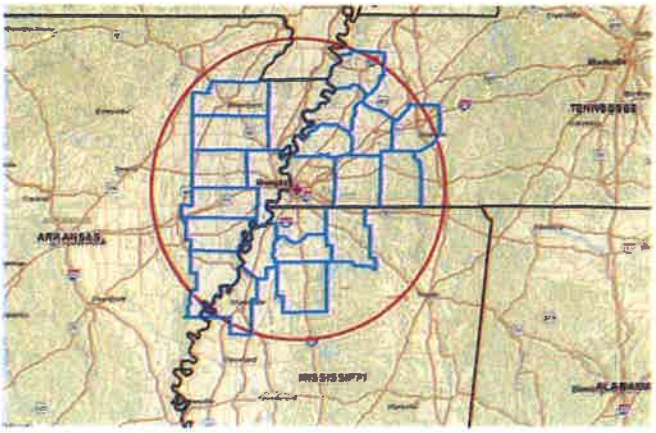
   b. **The applicant should demonstrate that the existing physical plant's condition warrants major renovation or expansion.**

The applicant is presenting the detailed justification for this onsite replacement and modernization project in this section of the application. Both a. and b. above are responded to in the narrative and exhibits beginning below.

DEMAND FOR THE PROJECT

Methodist Le Bonheur Healthcare is an integrated, not-for-profit healthcare system based in Memphis, Tennessee, with locations and partners across the Mid-South. Methodist is one of Tennessee's largest healthcare providers, serving populations of diverse socio-economic status across a broad geographic service area spanning West Tennessee, North Mississippi, and East Arkansas. Methodist Healthcare's primary acute care organization, Methodist Healthcare-Memphis Hospitals, is the applicant for this CON. Methodist Healthcare-Memphis Hospital owns and operates five Shelby County hospitals under a single general hospital license. The largest of the facilities, Methodist University Hospital, is the focus of this application.

As the system's tertiary academic medical center, Methodist University Hospital, located in the downtown medical center, is well positioned to serve the expansive tri-state service area. Through the partnership with the University of Tennessee Health Science Center, Methodist helps train the next generation of medical professionals and brings cutting-edge research and treatment to area patients. Methodist University is committed to education and advancements in clinical care and as such is a vital organization to the downtown medical district and broader tri-state area.



Methodist remained loyal to the inner city and mission markets even as competitors and other healthcare resources followed the population shift to the east. With this project, Methodist affirms an unwavering vision for the downtown market with plans to invest over $280 million dollars in the health and well-being of all Memphians and surrounding counties.

As noted previously in the application, this proposal is an onsite replacement and modernization project of the campus of Methodist University Hospital. Methodist University was chartered by the Methodist Church in 1924 to provide high-quality, affordable healthcare in accordance with the church's mission and principles. The original 125-bed building was a single four-story structure located on this Union Avenue site. In the first year, the hospital treated a little over 3,100 patients.

More than 90 years later, Methodist University treats over 18,000 inpatients and 70,000 emergency patients annually. The campus grew with the population and healthcare demands of the inner city and surrounding region to 617 beds, twenty operating rooms, and fifty-six emergency room beds/bays. The current campus is expansive with both inpatient and outpatient services interspersed and spread across a complex of buildings spanning six blocks and almost nineteen acres. Expansion occurred over decades and the older buildings on the campus – those built 1950-70 – pose serious challenges for today's clinical standards and state-of-the art technology. Conditions in the older buildings are not conducive to Methodist's trademark patient and family centered care. While outdated and not optimal for patient-direct clinical services and beds, the older buildings are better suited for the relocation of growing education, support, and academic functions.

Each addition and plan for growth for the Methodist University campus has been intentional, strategic, and well designed. However, healthcare delivery has changed so much since Methodist University was constructed that significant changes are now necessary. For the last decade, new technologies, care delivery methods, and payment models have shifted inpatient volumes to ambulatory settings. Financial pressures focusing on population health and reductions in readmissions and avoidable admissions are incentivizing providers to engage patients earlier with more accessible and coordinated care options. At the same time, the baby boomers are aging, chronic disease is more prevalent, and patients seen in hospital emergency rooms and inpatient settings are sicker requiring more complex treatment plans and high acuity centers of excellence such

as transplant, cancer, neurology and cardiovascular. The campus needs major renovation and modernization to meet twenty-first century standards. Over the last nine months, Methodist completed a comprehensive assessment of the campus infrastructure and updated the master plan to meet long term vision for the hospital and health system.

The planning priorities for the assessment are outlined below and details on findings and solutions follow as justification for this project:

- Consolidate currently disjointed clinical services to support institute goals and operational efficiencies - Transplant, Cancer, Neurosciences, and Cardiovascular services
- Improve ability for support services to efficiently service clinical areas
- Improve provision of outpatient services to support patient convenience and efficiency
- Enhance campus organization with better defined zoning, access points, and wayfinding
- Provide space to accommodate additional capacity and to support changing care models – shift to outpatient status and higher acuity inpatients
- Upgrade facilities to support high quality care, patient experience, ongoing physician recruitment, and medical education
- Provide flexibility to accommodate a rapidly changing health care environment
- Recycle aging infrastructure

Consolidate disjointed clinical services and improve efficiency of support services

As the system's tertiary referral center, Methodist University is a leader in specialized medicine for complex diseases, illnesses and injuries. Methodist University has one of the largest neurosciences programs in the country, has a regionally active cardiovascular center, is the region's comprehensive leader in adult cancer care through its partnership with West Cancer Center, and is home to the nationally recognized Methodist University Transplant Institute. These blue chip services are fragmented and spread throughout the oldest buildings on campus including Thomas wing which was built in 1966 and the Service and East wings which were built in 1958.

The fragmented clinical services hinder access to care, complicate patient navigation, and detract from a multi-disciplinary care approach. This project will consolidate disjointed transplant and oncology clinical services adjacent to imaging, lab, pharmacy, surgical, and inpatient units. Methodist believes an investment in the future of Methodist University Hospital required a critical review of all clinical program priorities, inpatient capacity, outpatient services, support services, and a look at the entire campus organization.

Transplant

The University of Tennessee (UT) has a long, rich history of solid organ transplantation. It has been forty years since the first kidney transplant was performed in Tennessee. UT became only the third Transplant program in the United States to perform a liver transplant in 1982. The UT program partnered with Methodist LeBonheur Healthcare in 2004 and formed the Methodist University Hospital Transplant Institute (MUHTI). More than 1,000 liver transplants and 1,000 kidney transplants have been performed at MUHTI and Le Bonheur Children's Hospital since 2006. MUHTI serves the highest percentage of minority patients in the country and has the only pediatric liver transplant program in the underserved Mid-South (TN, AR, and MS).

The experience of receiving a transplanted organ is unlike any other patient experience. Patients and their loved ones come to the Institute stressed and anxious. They are embarking on a lifelong journey with the transplant care team. From pre-transplant testing through the wait for an organ and then to life changing transplant surgery, the Institute serves as a home away from home. As patients return again and again for post-transplant medical, social, psychological and spiritual support, the importance of a comprehensive care center as a home becomes even more critical. That's why we are committed to completely re-thinking and re-doing the clinical space and campus that are the setting for this journey.

The Methodist University Hospital Transplant Institute is renowned worldwide with the most experience in steroid-free liver transplantation in the world. The Institute ranks among the top 10 liver transplant programs, the top 15 overall transplant programs in the nation, and has performed over 6,000 transplants. The care we provide our transplant patients is extraordinary, but the facility where those patients receive care is not. This shortcoming is particularly significant for transplant patients and their families who must visit repeatedly for pre-transplant testing, the transplant surgery itself, and lifelong post-surgical care. This enduring connection to the Transplant Institute makes it imperative that the facility be patient-and-family centered, focused in a warm and inviting space with integrated inpatient and outpatient service offerings in a single building.

Cancer

Over the last decade, the cancer care landscape has changed dramatically, with new advances and treatments, changes in reimbursement, and the continued threat of regulatory driven health care reform. These threats are occurring while the same provider community is facing a significant projected increase in the number of cancer patients due to an ever-aging population. This anticipated increase in cancer patients could cripple the current cancer delivery system. Methodist recently adopted a collaborative, integrated multidisciplinary strategy in the east market to resolve fragmentation. The West Cancer Center opened in November 2015 is exceeding expectations. Yet, a significant portion of cancer care delivery in the downtown market is still fragmented. Chemotherapeutic infusion, radiation oncology, cancer specific surgery, interventional radiology, and medical oncology services are still delivered in different locations with weak coordination of efforts and collaboration. This project will replicate the same integrated approach on the Methodist University Campus.

Cancer providers that clearly and efficiently develop and operationalize this approach will create higher standards of care, complex treatment options, better research opportunities and access to multi-phase clinical trials. This type of care program will increase patient's knowledge and care expectations by experiencing a system designed to reduce or eliminate disparate experiences of care. Many studies show that fragmented care delivery, i.e. patients treated by multiple providers at multiple locations, will not be able to provide an enhanced quality of care with the expected changes in reimbursement and the expected increase in patient volume.

From a planning perspective, a multidisciplinary cancer program is a complex and difficult challenge that calls for a strategic and collaborative approach. The Advisory Board Oncology Roundtable's 2007 Patient Experience Survey discovered that patients point to a multidisciplinary approach to cancer care as "the most valued service." Methodist's response to the challenge was in collaboration with The West Clinic and the UTHSC. In 2011, the West Clinic combined forces with Methodist and the UTHSC to transform cancer care in the Mid-South. The strengths and cultures of all three organizations are leveraged in the development of a fully integrated cancer program which will expand collaborative efforts in cancer research and education with a vision toward personalized precision cancer care.

Oncologists have always played the key role in cancer care, and no matter what, the success of a multidisciplinary program depends on the skills and competencies of the supporting care team. The West Clinic is the region's premier provider of cancer care and is a nationally-recognized leader in cancer research. Over the past thirty-three years West Clinic has built an expert team dedicated to excellence and compassionate care. The West Clinic currently has over thirty physicians in multidisciplinary specialties and multiple locations in Tennessee, Mississippi and Arkansas providing services to include medical oncology/hematology, gynecologic oncology, blood cell transplants, breast surgery, diagnostic and interventional radiology, metabolic bone disease/endocrinology, clinical psychology, pain and palliative care, radiation oncology, comprehensive breast center, nutritional counseling, ACORN research and the WINGS Cancer Foundation. The multi-disciplinary team includes pharmacists, nurses, clinical technicians, social workers and patient care coordinators/navigators. The full care team is committed to working collaboratively to ensure a seamless treatment program.

The specific mission of the applicant with regard to cancer is to develop an integrated comprehensive cancer care program will reduce the disparity between national cancer mortality rates and those of Shelby County. Such a program will allow for Methodist to prepare for the anticipated increase in cancer as the population ages. There are double digit growth rates for the Methodist service area in the next decade.

Methodist University Hospital's focus areas must not only include transplant and cancer but also neurosciences and cardiovascular services, in addition to being the primary community provider in the geography. Methodist University's presence in high priority programs will require improving adjacencies and addressing inadequate and inefficient space and equipment, both on the inpatient and outpatient side.

Improve outpatient services and enhance campus organization
As the outpatient market has grown with advances in technology, the move towards population health, and the industry shift from volume to value, hospital leaders have responded by expanding ambulatory services. Outpatient programs are a way to expand traditional areas of expertise and prevent costlier illnesses and complications later. There are currently over twenty outpatient access points on the Methodist University campus. With this project, the system will reorganize and streamline the ambulatory care delivery process.

As noted in Diagram 3 below, outpatient services (red dots) are currently scattered across the campus with multiple access points which makes wayfinding, parking, and movement around the hospital a challenge. Diagram 4 shows the multiple access points on all sides of the campus, complex circulation patterns with access off all major roadways surrounding the campus, and the lack of clear separation of patient/visitor, staff, and material flows.

DIAGRAM 3
METHODIST UNIVERSITY CAMPUS
CURRENT STACKING DIAGRAM

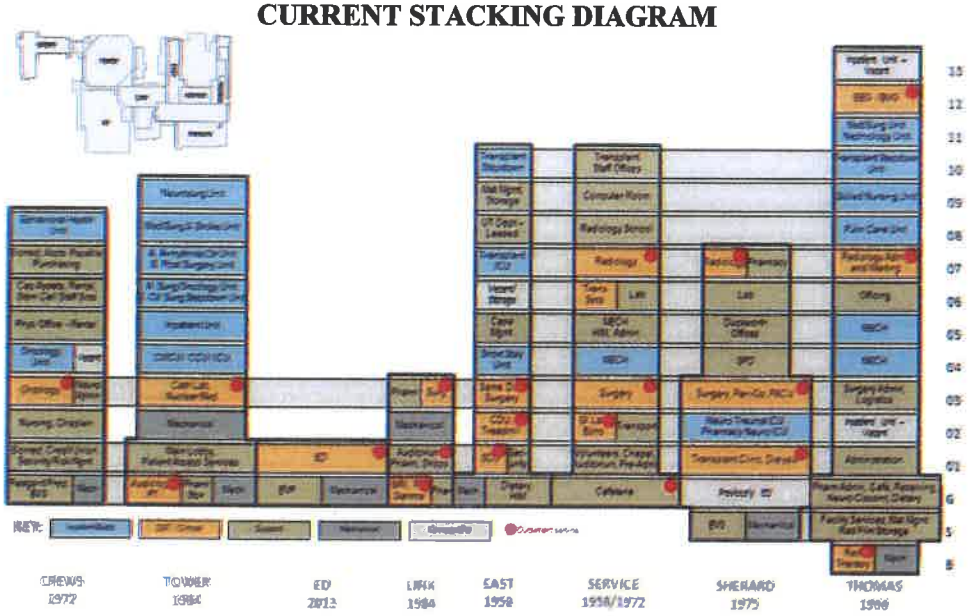


DIAGRAM 4
METHODIST UNIVERSITY CAMPUS
CURRENT SITE ACCESS AND CIRCULATION

The new ambulatory building will co-locate high traffic outpatient services such as imaging, ambulatory surgery, infusion, dialysis, and clinic space for transplant and oncology in a single building. The new construction provides a more accessible, concentrated presentation of outpatient services. The project will enhance campus organization with better defined zoning, access points, and wayfinding. The new ambulatory building will have direct access to parking and separate inpatient and outpatient flows with a new flexible design to accommodate a rapidly changing health care environment.

Upgrade facilities and provide space to support changing care models
Methodist is committed to creating an environment that values the individual differences and unique contributions of everyone touched by the organization. Rooted in the fact that no one knows patients better than their family and friends, Methodist encourages family participation in care and planning. The system's Family Partner Council is now a volunteer team of more than 150 former patients and caregivers that act as an advisory group and provide insights to help transform care delivery. While Methodist is known for embracing these concepts, the improvement of patient experience is endorsed by the Centers of Medicare and Medicaid Services (CMS). In 2015, CMS tied 1.5% of Medicare reimbursement to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. The HCAHPS scoring is based on eight key issues: nurse and doctor communication, quietness, information about medications, discharge information, cleanliness, responsiveness, pain management, and transitions in care. On the Hospital Compare website, Methodist Healthcare currently has an overall (summary) rating of four stars in regards to patient experience, with the majority of the measures at a four-star level and the rest at a three-star level. This project will benefit patient experience across all domains but particularly areas like communication, cleanliness, and care transitions, where there's opportunity for improvement.

The outdated facilities on the Methodist University campus present challenges to the patient experience and the patient and family approach to care. Some of those challenges include 1) the restrictive size of patient rooms in the oldest buildings which do not provide adequate space for family members to engage with physicians and clinicians in the care plan, 2) the presence of shared showers in some nursing units in the Thomas and East buildings which is a dissatisfier for patients and families, and 3) the antiquated facility design that does not meet today's acoustic standards for noise control.

Additionally, the aging infrastructure creates inefficiencies in operations and presents barriers for twenty-first century technology. As an example, the limited space on nursing floors restricts the use of omnicell units, automated, secure medication cabinets. Omnicell units improve nursing and pharmacy workflow, minimize redundant data entry, and improve security and quality. There are complications to renovating the oldest buildings to adapt to newer technology due to column spacing and floor to ceiling heights. The proposed new construction will resolve these concerns and provide the necessary space for state-of-the art technology and modern healthcare.

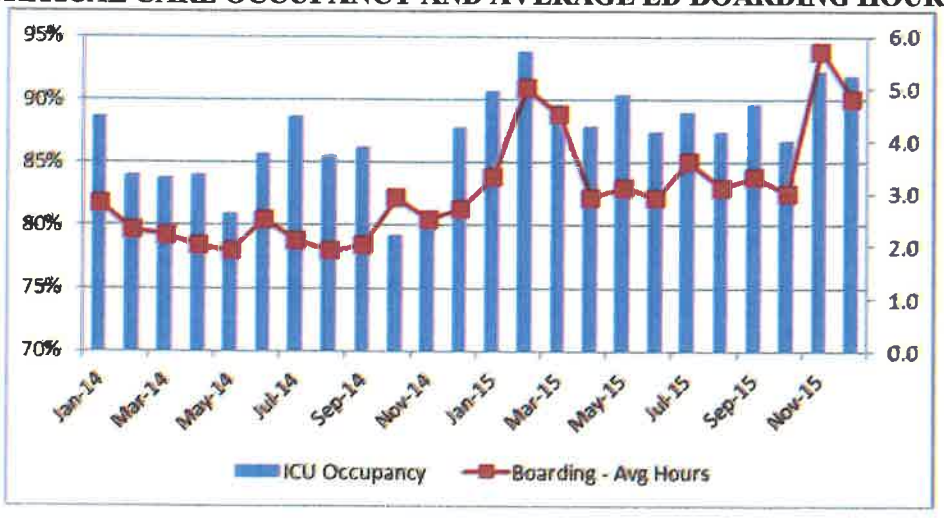
Methodist University is the core teaching hospital for University of Tennessee Health Science Center. The hospital's academic focus offers highly specialized services for complex diseases, illnesses, and injuries, develops technology, and carries out research to improve lives. The regional and national outreach of the academic programs is shifting the need for more intensive medical capacity and need for a state-of-the-art facility.

An internal study conducted on occupancy rates for a period during 2014-2015 for critical care beds, shows all units have the lowest rating due to high occupancy rates at 82% or higher against an industry benchmarks of 75%. See Table 4 below for summary results per critical care unit. Patient flow from the emergency department to the critical care units is delayed by the lack of beds. Methodist University has experienced a growth in number of patients being held in the emergency room as well as an increase in wait times. See Table 4 below denoting the correlated delays as critical care beds reach beyond optimal occupancy rate. Again, patient experience suffers along with the delays and inefficiencies related to lack of capacity.

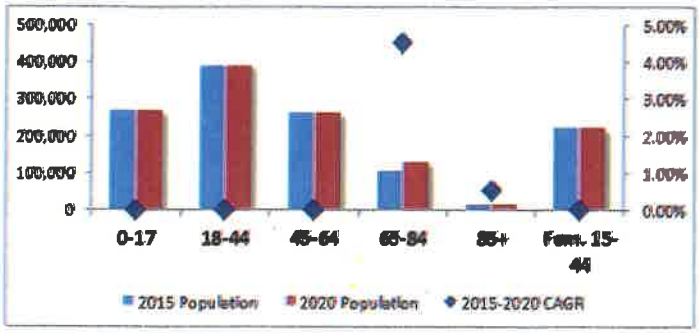
TABLE 4
METHODIST UNIVERSITY
CRITICAL CARE OCCUPANCY AND AVERAGE ED BOARDING HOURS

Category of Service	Cost Center	Unit	2014-15 Annualized ADC	Staffed Beds	Current Occupancy	Benchmark Occupancy		Inpatient Capacity Rating	With Observation		
						Low	High		ADC	Occ	Rating
ICU			63.38	72	88.0%	70%	75%	1	63.45	88.1%	1
ICU	16097	Med/Surg ICU 4 East	6.72	8	84.0%	70%	75%	1	6.72	84.0%	1
ICU	16121	Medical ICU	14.65	16	91.6%	70%	75%	1	14.66	91.6%	1
ICU	16124	Surgical ICU	7.21	8	90.1%	70%	75%	1	7.22	90.3%	1
ICU	16125	Neuro Critical Care	14.31	16	89.4%	70%	75%	1	14.33	89.6%	1
CVS	16128	CV ICU 2 Sherard	13.86	16	86.6%	70%	75%	1	13.89	86.8%	1
ICU	17136	7 East - Transplant ICU	6.63	8	82.9%	70%	75%	1	6.63	82.9%	1

TABLE 5
METHODIST UNIVERSITY
CRITICAL CARE OCCUPANCY AND AVERAGE ED BOARDING HOURS



While the overall population is remaining fairly flat, the 65-84 age cohort is experiencing an annual growth rate over 4%; this will increase demand for services utilized by older populations. There are rising numbers of chronically ill patients in need of more intensive hospital services. Fortification of critical care resources supporting inpatient and subspecialty care programs in transplant, oncology, neurology, and cardiovascular is imperative for Methodist University Hospital as the system's academic tertiary flagship.

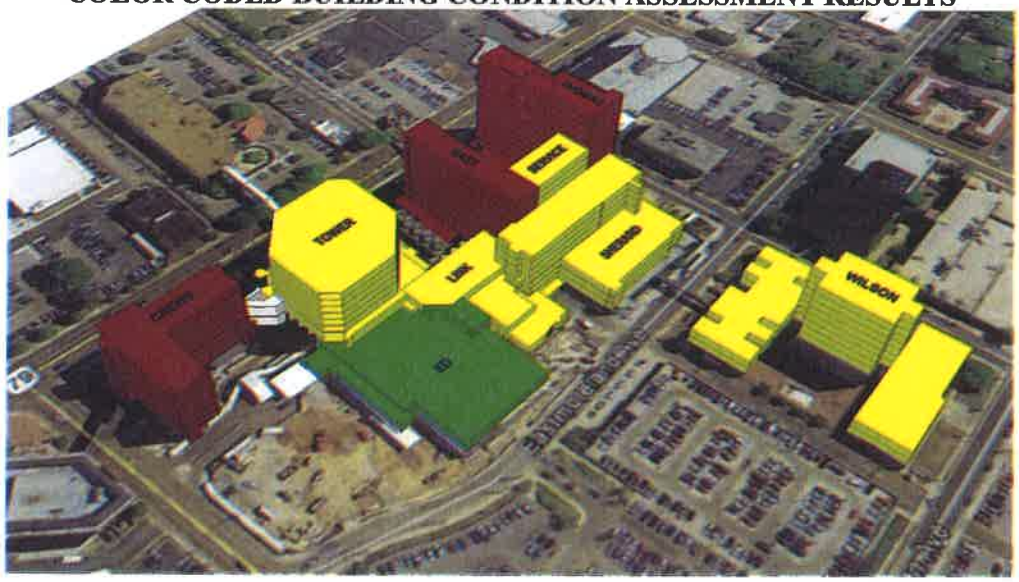


Recycle aging infrastructure and provide flexibility

The Methodist University campus is landlocked. Many buildings housing direct patient care services were built 50-60 years. As part of the master planning process, Methodist assessed the physical condition of each building on the main campus. The assessment included the evaluation of structural, mechanical, and electrical components as well as the age, presence of asbestos and overall functionality. The physical plant alone warrants the need for the project.

Please note in Diagram 5 below the findings of the assessment with the stop light colors representing good (green) to poor (red) conditions. The project proposes to relocate patient beds and acute care services from the Thomas and East buildings as well as Crews. The Crews building is also slated for demolition.

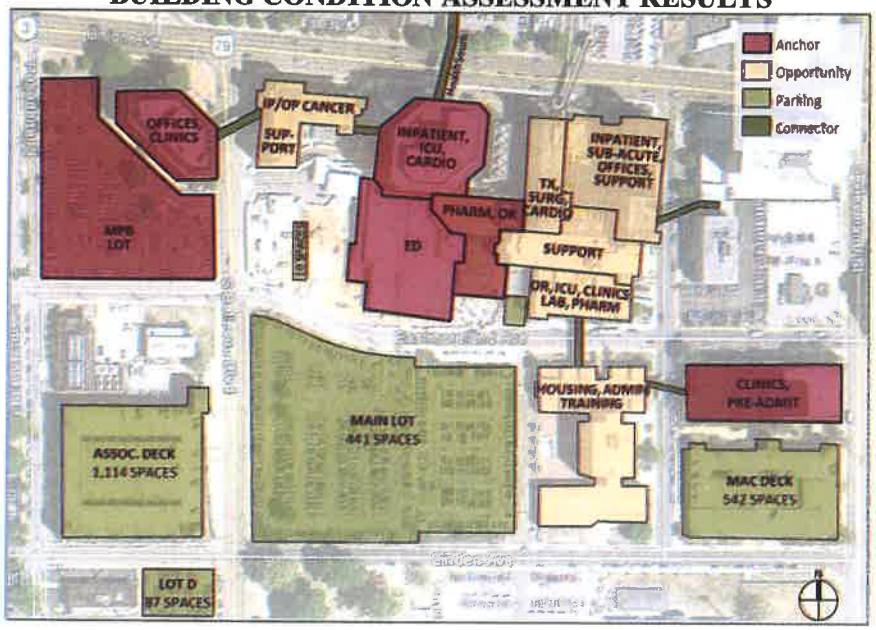
DIAGRAM 5
METHODIST UNIVERSITY HOSPITAL
COLOR CODED BUILDING CONDITION ASSESSMENT RESULTS



Another view of the campus developed during the master planning process and assessment of the building conditions, denotes the anchors of the campus as the existing patient tower, emergency department opened in 2014, the Link building, and adjacent medical professional offices. From a consumers perspective the two prime corners on Union Avenue are occupied by the lowest ranking buildings, Thomas and Crews. Please note in Diagram 6 below shows the building assessment. Plans call for future campus development to focus on the anchoring buildings. This project relocates direct patient care to the anchoring buildings and the new patient

tower to modernize the campus and establish a sustainable foundation for the system's academic medical center, Methodist University Hospital.

DIAGRAM 6
METHODIST UNIVERSITY HOSPITAL
BUILDING CONDITION ASSESSMENT RESULTS



Since inception, the system has remained affiliated with the United Methodist Church and steadfast in a faith which inspires service to patients and dedication to improving the health of our entire community. Methodist Healthcare is an integrated health care delivery system, dedicated to the art of healing through our faith-based commitment to minister to the whole person. Methodist remains committed to the patients and families in tri-state area and proposes to make this investment to provide accessible, efficient, and high quality services with the new a state-of-the-art facility.

Project-Specific Review Criteria: Position Emission Tomography

1. **Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter.**

   The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

   For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

   Not Applicable; the project is a relocation and replacement of existing PET services. The original PET was approved under the former CON guidelines requiring 750 procedures in the first year.

2. **All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population.**

   Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

   Not Applicable; the project is a relocation and replacement of existing PET services.

3. **All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.**

   PET/CT imaging is a unique service that is not replicated by lower cost technology. The applicant currently owns and operates the PET, and this project is the relocation and replacement of the existing service within 1 mile of the current location.

   The investigation of shared services and lower cost technology found no alternatives that were more advantageous in terms of accessibility, availability, continuity, cost, and quality of care. Methodist's existing PET service is an integral part of the comprehensive West Cancer program based at Methodist University Hospital, and is a vital part of the oncology resources in the Memphis Medical Center. In partnership with physician partners and staff, Methodist evaluated alternatives.

4. **Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.**

   Not Applicable; the project is a relocation and replacement of existing fixed PET services.

5. **A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelvemonth period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:**

   Stationary Units: Eight (8) procedures/day x 250 days/year = 2,000 procedures/year

   Not Applicable; the project is a relocation and replacement of existing PET services.

6. **The applicant should provide evidence that the PET unit is safe and effective for its proposed use.**
   a. **The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.**

      See Attachment B:II (E)(E)(4) for FDA certification.

   b. **The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.**

The architect consulted on this project confirms that the physical environment will conform to all applicable federal standards, manufacturer's specifications and licensing agencies' requirements. See Attachment C: Economic Feasibility (1)(d) for the architect's letter.

c. **The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.**

The unit will be on the Methodist University Hospital campus. There are clinical technicians and emergency personnel on the premises trained in basic life support when the patient is being scanned. In the event of cardiac or respiratory arrest, trained clinical personnel will initiate basic life support while the patient is being emergently removed from the scan room, and then taken to be treated by appropriate physicians and clinicians.

d. **The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.**

There are established standard protocols in place for Methodist Healthcare to ensure all PET/CT procedures are medically necessary and will not unnecessarily duplicate other services PET/CT procedures are typically performed to assess the possibility of infection or malignancy. Methodist has a dedicated team of nurses that precert all PET/CT scans through the various third party payers. The rigorous precert process ensures medical necessity and assures that the patient does not receive duplicative procedures. Additionally, all procedures require a physicians' order just as all PET/CT scans require a precert. See Attachment 6 (d) for the System Policy outlining the guidelines for a physician order for all diagnostic services.

e. **The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.**

The medical director for the PET/CT operations is Board Certified in Diagnostic Radiology - General and Nuclear Radiology - Subspecialty. See Attachment 6 (e)(1) for Medical Director's Curriculum Vitae and Attachment 6 (e)(2) for the documentation of the scope of the medical director's duties and responsibilities.

There is and will be a board certified radiologist experienced and trained in PET/CT imaging procedures to supervise staff and interpret studies. Current credentialed physicians will provide clinical supervision and interpretation services. All physicians are licensed to practice medicine in the state of Tennessee, are board certified in Nuclear Medicine or Diagnostic Radiology, and have appropriate licensure for handling medical isotopes and radiopharmaceuticals. The interpretation services will be provided by physicians with additional experience, credentialing, and/or board certification.

f. **All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical**

director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

The need for a transfer agreement is not applicable; the PET unit will be located on the Methodist University Hospital campus.

There is one medical staff for Methodist Healthcare – Memphis Hospitals, and the medical director is currently an active member of the medical staff

7. **The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.**

   Methodist assures the HSDA that all data requested to maintain the Equipment Registry will be submitted within the expected time frame.

8. **In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:**

a. **Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;**

   Not Applicable.

b. **Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;**

   Not Applicable.

c. **Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or**

   Not Applicable.

d. **Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.**

   Methodist is certified for both Medicare and TennCare/Medicaid and participates in both programs. Methodist Healthcare–Memphis Hospitals contracts with all three TennCare plans offered in the service area and with Medicaid in adjoining States. All hospitals including the hospital-based PET ambulatory services treat TennCare participants under the system's TennCare contracts.

   In comparison to other large counties across the State, Shelby County is the home to a disparate number of low-income or disabled Tennesseans seeking coverage from the state's Medicaid program. Methodist is the largest healthcare providers of TennCare and is committed to these patients as reflected in the projections for this proposal.

b. **Applications that include a Change of Site for a health care institution, provide a response to General Criterion and Standards (4)(a-c)**

Not applicable. This project is not requesting a change of site.

2. **Describe the relationship of this project to the applicant facility's long-range development plans, if any.**

Methodist Le Bonheur Healthcare's mission is to partner with its medical staffs and collaborate with its patients and families to be the leader in high quality, cost effective healthcare in all sectors of the Greater Memphis-Shelby County service area. Methodist Healthcare has strategically placed and maintained hospital and ambulatory facilities in all quadrants of Shelby County as part of that mission, to provide multiple entry points to acute care for communities of varied social and economic characteristics. Methodist University Hospital is the system's tertiary academic medical center located in the center of the service area in downtown Memphis. The project is a reinvestment in the downtown academic presence with anchoring cancer and transplant centers of excellence. Methodist aims to leverage the partnership with UTHSC to improve the health of the overall community and raise the level of medical practice for adults and pediatrics.

The approval and completion of the project is key to the fulfillment of the system's long-term financial and strategic commitments to its service area.

3. **Identify the proposed service area <u>and</u> justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. Please submit the map on 8 1/2" x 11" sheet of white paper marked only with ink detectable by a standard photocopier (i.e., no highlighters, pencils, etc.).**

The project primary service area includes Shelby, Fayette and Tipton counties in Tennessee, DeSoto County in Mississippi, and Crittenden County in Arkansas. The secondary service area includes Tipton, Fayette, Lauderdale, Hardeman, Haywood, Dyer, and Madison Counties in Tennessee, Marshall, Tunica, Panola, Tate, and Coahoma Counties in Mississippi, and St. Francis, Mississippi, Poinsett, Lee, Phillips, and Craighead Counties in Arkansas. See Attachment Section C: Need (3) for a county level service area map. This service area is deemed reasonable.

4. **A. Describe the demographics of the population to be served by this proposal.**

The primary service area includes Shelby County in Tennessee, Desoto County in Mississippi, and Crittenden County in Arkansas. The population of the primary service area is projected to approach 1.2 million people by 2020 which is a growth rate of 2% (over 27,000 people) over the next five years.

The secondary service area includes Tipton, Fayette, Lauderdale, Hardeman, Haywood, Dyer, and Madison Counties in Tennessee, Marshall, Tunica, Panola, Tate, and Coahoma Counties in Mississippi, and St. Francis, Mississippi, Poinsett, Lee, Phillips, and Craighead Counties in Arkansas. The population of the service area is projected to exceed 690,000 people by 2020 which is a growth rate of 0.32% (just over 2,000 people) over the next five years.

The total service area for this project is projected to exceed 1.8 million people by 2020 with a 2% overall growth rate. See Tables 6-9 for details of the population demographics. The secondary service area charts are split by state for readability.

TABLE 6
PRIMARY SERVICE AREA AND SECONDARY SERVICE AREA TOTALS
2015–2020 POPULATION PROJECTIONS, BY COUNTY

Demographic Variable/ Geographic Area	Shelby County	DeSoto County	Crittenden County	Primary Service Area Total	Secondary Service Area Total	Total Service Area
Total Population-2015	946,637	168,989	48,531	1,164,157	688,259	1,852,416
Total Population-2020	966,405	177,125	47,633	1,191,163	690,456	1,881,619
Total Population-% change	2%	5%	-2%	2%	0%	2%
Age 65+ Population-2015	112,613	20,140	5,922	138,675	101,398	240,073
Age 65+ Population-2020	137,447	24,548	6,721	168,716	115,283	283,999
Age 65+ Population-% change	22%	22%	13%	22%	14%	18%
Age 65+ Population-% of Total – 2015	12%	12%	12%	12%	15%	13%
Median Household Income (2015)	$46,250	$58,505	$37,751	n/a	n/a	n/a
TennCare Enrollees	272,076	n/a	n/a	272,076	79,252	351,328
TennCare Enrollees- % of Total Pop. (2015)	29%	n/a	n/a	n/a	n/a	n/a
Persons Below Poverty Level (2015)	196,900	16,561	12,764	226,225	152,264	378,489
Persons Below Poverty Level- % of Total Pop. (2015)	20.8%	9.8%	26.3%	19.4%	22.1%	20.4%
Source: Market Expert – Claritas Data, U.S. Census Bureau Poverty Estimates and TennCare Enrollment Data						

TABLE 7
SECONDARY SERVICE AREA IN TENNESSEE
2015–2020 POPULATION PROJECTIONS, BY COUNTY

Demographic Variable/ Geographic Area	Tipton TN	Fayette TN	Lauderdale TN	Hardeman TN	Haywood TN	Dyer TN	Madison TN
Total Population-2015	59,918	34,845	29,336	26,770	16,473	36,721	97,990
Total Population-2020	60,955	35,920	29,623	26,072	16,160	37,029	99,834
Total Population-% change	2%	3%	1%	-3%	-2%	1%	2%
Age 65+ Population-2015	7,993	5,899	4,151	4,324	2,641	6,076	14,574
Age 65+ Population-2020	9,513	6,906	4,744	4,745	2,995	6,934	16,847
Age 65+ Population-% change	19%	17%	14%	10%	13%	14%	16%
Age 65+ Population-% of Total – 2015	13%	17%	14%	16%	16%	17%	15%
Median Household Income (2015)	$52,423	$56,618	$32,326	$30,973	$34,542	$38,953	$41,617
TennCare Enrollees	13,992	7,134	8,181	7,370	6,061	11,091	25,423
TennCare Enrollees- % of Total Pop. (2015)	23%	20%	28%	28%	37%	30%	26%
Persons Below Poverty Level (2015)	8,029	4,878	7,627	6,585	3,476	6,536	19,598
Persons Below Poverty Level- % of Total Pop. (2015)	13%	14%	26%	24.6%	21.1%	17.8%	20%
Source: Market Expert – Claritas Data, U.S. Census Bureau Poverty Estimates and TennCare Enrollment Data							

TABLE 8
SECONDARY SERVICE AREA IN MISSISSIPPI
2015–2020 POPULATION PROJECTIONS, BY COUNTY

Demographic Variable/ Geographic Area	Marshall MS	Tunica MS	Panola MS	Tate MS	Coahoma MS
Total Population-2015	40,276	10,649	35,236	28,688	24,428
Total Population-2020	39,873	10,572	35,081	28,258	23,318
Total Population-% change	-1%	-1%	0%	-1%	-5%
Age 65+ Population-2015	6,029	1,196	5,109	4,282	3,239
Age 65+ Population-2020	6,891	1,414	5,808	4,843	3,498
Age 65+ Population-% change	14%	18%	14%	13%	8%
Age 65+ Population-% of Total – 2015	15%	11%	14%	15%	13%
Median Household Income (2015)	$36,022	$31,446	$35,715	$41,494	$26,407
TennCare Enrollees	n/a	n/a	n/a	n/a	n/a
TennCare Enrollees- % of Total Pop. (2015)	n/a	n/a	n/a	n/a	n/a
Persons Below Poverty Level (2015)	8,941	3,227	8,915	5,307	9,331
Persons Below Poverty Level- % of Total Pop. (2015)	22.2%	30.3%	25.3%	18.5%	38.2%
Source: Market Expert – Claritas Data, U.S. Census Bureau Poverty Estimates and TennCare Enrollment Data					

TABLE 9
SECONDARY SERVICE AREA IN ARKANSAS
2015–2020 POPULATION PROJECTIONS, BY COUNTY

Demographic Variable/ Geographic Area	St. Francis AR	Mississippi AR	Pointsett AR	Lee AR	Phillips AR	Craighead AR	Cross AR
Total Population-2015	27,788	43,472	24,401	9,176	20,316	104,828	16,948
Total Population-2020	26,591	41,672	24,057	8,787	18,967	111,005	16,682
Total Population-% change	-4%	-4%	-1%	-4%	-7%	6%	-2%
Age 65+ Population-2015	3,846	5,904	4,255	1,511	3,388	14,022	2,959
Age 65+ Population-2020	4,138	6,448	4,685	1,585	3,508	16,559	3,222
Age 65+ Population-% change	8%	9%	10%	5%	4%	18%	9%
Age 65+ Population-% of Total – 2015	14%	14%	17%	16%	17%	13%	17%
Median Household Income (2015)	$30,873	$36,428	$32,089	$25,034	$26,737	$41,393	$38,085
TennCare Enrollees	n/a	n/a	n/a	n/a	n/a	n/a	n/a
TennCare Enrollees- % of Total Pop. (2015)	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Persons Below Poverty Level (2015)	7,892	10,825	6,857	2,890	6,806	21,595	2,949
Persons Below Poverty Level- % of Total Pop. (2015)	28.4%	24.9%	28.1%	31.5%	33.5%	20.6%	17.4%
Source: Market Expert – Claritas Data, U.S. Census Bureau Poverty Estimates and TennCare Enrollment Data							

Shelby County represents 81% of the 3-County primary service area, and 51% of the entire service area shown.

Over the next five years, there will be a dramatic increase in the area of residents aged 65 years and older. It is particularly significant that during this period, the area population aged 65 years and older--the group that most needs healthcare--will increase 22% or over 30,000.

B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

The special needs of the service area population significantly contribute to the projected volumes and planning for the project. The business plan takes into consideration the aging of the population, the large number/disparate mix of TennCare enrollees and the predominance of poor lifestyle throughout the service area.

Shelby County is one of the least healthy communities in the country, yet, one with significant health assets, providers and academic partners all well aligned with the MLH mission and vision. As a faith-based healthcare provider with an obligation to meet the community's healthcare needs, Methodist Healthcare views the tremendous needs in the community as opportunities.

As shown above, the population in the service area is projected to age with the baby boom generation with 22% growth in the Methodist service area projected for the next five years. The older age cohorts already account for 60% of the health care expenditures. Within this age group, chronic illness is prevalent. Such chronic medical conditions include heart disease, stroke, hypertension, diabetes, and cancer which all potentially require more intensive use of healthcare resources. Methodist University is well positioned to treat these community needs, yet has plans with this project to expand and advance these high-end services to reach more of the community in need.

The population identified by the project's service area is plagued by a predominance of disease and health risk factors.

- Tennessee has one of the highest heart disease mortality rates in the United States. Incidence of heart disease mortality is dramatically higher in the mid-south than in other regions. Death rates from heart disease (rate per 100,000 35+ 2007-2009 per CDC) in the Methodist service area is higher than state and national average with Tipton rates at 484.5, Fayette at 458.0 and Shelby at 450.0 as compared to Tennessee at 422.4 and the Nation at 359.1.
- There are similarly high mortality rates in stroke. Death rates from stroke (rate per 100,000 35+ 2007-2009 per CDC) in the Methodist service area is higher than state and national average with Tipton rates at 105.4, Fayette at 101.2 and Shelby even higher at 112.9 as compared to Tennessee at 98.9 and the Nation at 78.6.
- Based on recent data from the Center for Disease Control and Prevention (based on self-reported prevalence by State), the South has the highest prevalence of obesity (29.5%), followed by the Midwest (29.0%), the Northeast (25.3%) and the West (24.3%). Obesity-related conditions include heart disease, stroke, 2 diabetes and certain types of cancer. From Methodist's tristate service area, Mississippi ranks highest in the nation at 34.9%, Arkansas is in the top 10 at 30.9% and Tennessee is no longer in the top 10 at 29.2%. A dated report entitled "F as in Fat: How Obesity Threatens America's Future 2010" rated Tennessee as the 2nd highest state in the country in obesity (under different methodology. Under these criteria, the Memphis TN-AR-MS Metropolitan Statistical Area had an obesity rate of 35.8% as compared to the Tennessee rate of 31.7% and National median rate of 27.5%. These trends will continue with the growing numbers of people who do not get regular physical activity.

Shelby County claims the largest population of all 95 Tennessee counties with almost 950,000 residents; with that Shelby County also has the largest TennCare population. The number of enrollees is twice that of any other county in the state; 29% in the county is enrolled in TennCare. Methodist is committed providing healthcare services to these patients as reflected in the projections for this proposal.

5. **Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.**

In the project's Tennessee primary service area, there are eleven adult acute care hospitals (including Methodist University) with a total of 3,844 licensed beds of which almost 80% were staffed (or 3,042 beds) in 2014. The average daily census for the market in 2014 was 2,704 (or 70% occupancy). There were 125,256 inpatient discharges and 716,500 inpatient days during this period.

ADULT GENERAL HOSPITALS
TENNESSEE PRIMARY TN SERVICE AREA
UTILIZATION OF BEDS, 2012-2014

	Methodist Germantown			Methodist South			Methodist North			Methodist University		
	2012	2013	2014	2012	2013	2014	2012	2013	2014	2012	2013	2014
Total Beds	309	309	309	156	156	156	246	246	246	617	617	617
Staffed Beds	309	309	309	144	144	143	207	224	222	416	416	428
Discharges	16,089	17,217	17,813	6,954	6,814	6,354	10,971	11,127	10,803	18,230	17,159	17,862
Pat. Days	73,419	77,483	78,586	29,938	29,324	24,700	62,286	61,923	57,517	120,042	117,668	114,319
ADC	276	292	297	113	111	93	234	234	217	451	444	431
Occupancy	89.3%	94.6%	96.0%	72.1%	70.9%	59.7%	95.2%	95.0%	88.2%	73.1%	72.0%	69.9%

	Baptist Memphis			Baptist Women's			Baptist Collierville			Regional One		
	2012	2013	2014	2012	2013	2014	2012	2013	2014	2012	2013	2014
Total Beds	706	706	706	140	140	140	81	81	81	631	631	631
Staffed Beds	573	545	547	140	140	140	81	81	81	294	303	309
Discharges	25,440	24,509	24,737	6,806	6,219	6,098	2,451	2,202	2,372	12,928	12,709	12,392
Pat. Days	170,707	163,128	155,576	27,052	25,016	24,154	9,655	8,474	9,352	90,277	91,539	87,930
ADC	642	616	587	102	94	91	36	32	35	339	345	332
Occupancy	90.9%	87.2%	83.2%	72.6%	67.4%	65.1%	44.8%	39.5%	43.6%	53.8%	54.7%	52.6%

	St. Francis Park			St. Francis Bartlett			Delta			Total TN PSA		
	2012	2013	2014	2012	2013	2014	2012	2013	2014	2012	2013	2014
Total Beds	519	519	519	196	196	196	243	243	243	3,844	3,844	3,844
Staffed Beds	500	494	494	196	196	196	170	173	173	3,030	3,025	3,042
Discharges	14,295	15,492	15,982	6,430	6,728	6,383	3,965	3,836	4,460	124,559	124,012	125,256
Pat. Days	85,557	87,370	88,021	33,137	31,786	31,118	33,171	38,869	45,227	735,241	732,580	716,500
ADC	322	330	332	125	120	117	125	147	171	2,764	2,764	2,704
Occupancy	62.0%	63.5%	64.0%	63.6%	61.2%	59.9%	51.3%	60.4%	70.2%	71.9%	71.9%	70.3%

6. **Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.**

Methodist University Hospital
Actual and Projected Adjusted Patient Days
2013 - 2020

	Actual 2013	Actual 2014	Actual 2015		Projected Year 1 2019	Projected Year 2 2020
Adjust Patient Days	209,280	203,524	213,748		223,139	223,110
Annual Change Rate		-2.75%	5.02%		4.40%*	0.00%
*Change Rate between 2015 and 2019 shows the four year change which equals a very conservative 1.1% year over year growth.						

Methodology Assumptions:

- This is a replacement project so projections are conservative following normal course of business and budgeted utilization.
- Adjusted patient days are projected for historical and projected financial statements. Adjusted Patient Days are calculated based on the ratio of gross outpatient revenue to inpatient revenue per inpatient day. The result, which represents the number of patient days attributable to outpatient services, is added to the number of inpatient days.

(Gross Outpatient Revenue / (Gross Inpatient Revenue / Inpatient Days)) = Outpatient Days

Outpatient Days + Inpatient Days = Adjusted Patient Days

- Historical adjusted patient days are calculated based on gross inpatient and outpatient revenue and actual patient days per our historical financial statements.
- Projected adjusted patient day are calculated based on the project's projected gross inpatient and outpatient revenue and projected patient days. Patient days are assumed to increase five percent from 2015 to 2019 and 2020 patient days remaining flat. An annual four percent rate increase is assumed for gross inpatient and outpatient revenues.
- See table below for in patient days chart for historical and projected.

Methodist University Hospital
Actual and Projected Adjusted Patient Days by Inpatient Bed Type
2013-2020

	Actual	Actual	Actual	Yr 1 Projected	Yr 2 Projected
	2013	**2014**	**2015**	**2019**	**2020**
Total Beds	617	617	617	617	617
Patient Days **	117,668	114,319	123,048	127,988	127,547
ADC	322.4	313.2	337.1	350.7	349.4
Occupancy	52.2%	50.8%	54.6%	56.8%	56.5%
23 Hour Observation Days	7,290	10,497	8,725	9,259	9,303
ADC	20.0	28.8	23.9	25.4	25.4
Occupancy	3.2%	4.6%	3.9%	4.1%	4.1%
Adj Total Pat Days w/ 23 Hr Obs	124,958	124,816	131,773	137,247	136,850
Adj Total ADC w/ 23 Hr Obs	342.4	341.0	361.0	376.0	374.9
Adj Total Occupancy w/ 23 Hr Obs	55.5%	55.4%	58.5%	60.9%	60.6%
Medical/Surgical Beds	511	511	511	483	483
Patient Days	86,325	83,077	91,508	93,633	93,289
ADC	236.5	227.6	250.7	256.5	254.9
Occupancy	46.3%	44.5%	49.1%	53.1%	52.8%
23 Hour Observation Days	7,290	10,497	8,725	9,259	9,303
ADC	20.0	28.8	23.9	25.4	25.4
Occupancy	3.9%	5.6%	4.7%	5.3%	5.3%
Adj M/S Pat Days w/ 23 Hr Obs	93,615	93,574	100,233	102,892	102,592
Adj M/S ADC w/ 23 Hr Obs	256.5	255.7	274.6	281.9	281.1
Adj M/S Occupancy w/ 23 Hr Obs	50.2%	50.2%	53.7%	58.4%	58.0%
Critical Care Beds	72	72	72	100	100
Patient Days	22,212	22,797	23,570	26,329	26,232
ADC	60.9	62.5	64.6	72.1	71.7
Occupancy	84.5%	86.7%	89.7%	72.1%	71.7%
Psych Beds	34	34	34	34	34
Patient Days	9,131	8,445	7,970	8,026	8,026
ADC	25.0	23.1	21.8	22.0	21.9
Occupancy	73.6%	68.0%	64.2%	64.7%	64.5%

ECONOMIC FEASIBILITY

1. **Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.**

   - **All projects should have a project cost of at least $3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)**

     The CON filing fee calculated from Line D of the Project Costs Chart is $45,000; therefore a check for this amount accompanies the application.

   - **The cost of any lease should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater.**

     Not Applicable.

   - **The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.**

Equipment Type	Equipment	Maintenance (4 years)	Total Cost
iMRI	$ 3,959,767	$ 705,180	$ 4,664,947
Linear Accelerator	$ 2,636,000	$ 760,581	$ 3,396,581
Hybrid Operating Room	$ 1,972,443	$ 375,300	$ 2,347,743

   - **For projects that include new construction, modification, and/or renovation; documentation must be provided from a contractor and/or architect that support the estimated construction costs**

     A letter from the architect follows as Attachment C: Economic Feasibility (1)(d).

PROJECT COSTS CHART

A.	Construction and equipment acquired by purchase:		
	1.	Architectural and Engineering Fees	$ 11,200,000
	2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	10,000
	3.	Acquisition of Site	-
	4.	Preparation of Site	6,750,000
	5.	Construction Costs	172,150,000
	6.	Contingency Fund	18,245,000
	7.	Fixed Equipment (Not included in Construction Contract)	-
	8.	Moveable Equipment (List all equipment over $50,000)	50,900,000
	9.	Other (Specify) Technology and Soft Costs	20,700,000
B.	Acquisition by gift, donation, or lease:		
	1.	Facility (inclusive of building and land)	
	2.	Building only	
	3.	Land only	
	4.	Equipment (Specify) _____	
	5.	Other (Specify) _____	
C.	Financing Costs and Fees:		
	1.	Interim Financing	
	2.	Underwriting Costs	
	3.	Reserve for One Year's Debt Service	
	4.	Other (Specify) _____	
D.	Estimated Project Cost (A+B+C)		275,955,000
E.	CON Filing Fee		45,000
F.	Total Estimated Project Cost (D+E)	**TOTAL**	$ 280,000,000

2. Identify the funding sources for this project.

Please check the applicable item(s) below and briefly summarize how the project will be financed. ***(Documentation for the type of funding MUST be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.)***

	A.	**Commercial loan—Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;**
	B.	**Tax-exempt bonds—Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;**
	C.	**General obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.**
	D.	**Grants–Notification of intent form for grant application or notice of grant award; or**
X	**E.**	**Cash Reserves--Appropriate documentation from Chief Financial Officer.**
	F.	**Other—Identify and document funding from all other sources.**
		Methodist Healthcare is prepared to fund the project cost with cash reserves. See the attached letter from the Chief Financial Officer. Attachment C: Economic Feasibility (2)

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.

Total construction costs excluding site prep and construction contingency are $172,150,000 (or $366 PSF) with new construction costs of $166,692,019 (or $396 PSF) and renovation costs of $5,457,981 (or $111 PSF).

The costs of the project are higher than average due to the scope of the project yet reasonable as compared to similar renovations done throughout Methodist Healthcare over the last few years and on recently approved CON's.

TABLE 2
COST PER SQUARE FOOT COMPARISON WITH APPROVED PROJECTS

CON Name	Date Filed	Cost per Square Foot
Methodist South Hospital Renovate and Expand Emergency Department	**Mar-15**	**$ 209**
Methodist Memphis Hospital Establish West Cancer Center	**Nov-13**	**$ 145**
Le Bonheur Children's Hospital Establish Pediatric Outpatient Center	**Nov-13**	**$ 152**
Campbell Clinic Surgery Center Construction & Renovation	**Aug-12**	**$ 244**
The Regional Medical Center – The Med Hospital Construction & Renovation	**Aug-12**	**$ 225**
Baptist Memorial Women's Hospital ED Construction & Renovation	**Dec-12**	**$ 238**

Total construction costs are also higher when compared to the HSDA construction costs ranges. Renovation costs for the project are at the first quartile, yet new construction costs are above the third quartile. Please note that three years of escalation are costs built into the construction estimates given the project timeline which equate to roughly $50 PSF. Other factors that increase the costs projections for this project are:

- the new patient tower spans an active road
- the new patient tower will connect to existing facilities at several locations
- the site is not a greenfield site yet is an onsite modernization project in a busy campus

See the cost per square foot comparisons below.

TABLE 3
HOSPITAL CONSTRUCTION COST PER SQUARE FOOT
YEARS: 2012-2014

	Renovated Construction	New Construction	Total Construction
1st Quartile	$110.98/sq ft	$224.09/sq ft	$156.78/sq ft
Median	$192.46/sq ft	$259.66/sq ft	$227.88/sq ft
3rd Quartile	$297.82/sq ft	$296.52/sq ft	$298.66/sq ft

Source: CON approved applications for years 2012 through 2014

4. **Complete Historical and Projected Data Charts on the following two pages--*Do not modify the Charts provided or submit Chart substitutions!* Historical Data Chart represents revenue and expense information for the last *three (3)* years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the *Proposal Only* (*i.e.*, if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).**

Following this page are the Historic Data Chart for Methodist Le Bonheur Healthcare, and a Projected Data Chart for Methodist University Hospital.

5. **Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.**

The average gross charge and deduction amounts shown as a percent of adjusted patient days are below for 2019, the first year of operations.

Average Gross Charge	$	10,316
Average Deduction		7,842
Average Net Charge	$	2,474

HISTORICAL DATA CHART

Methodist LeBonheur Healthcare

Give information for the last *three (3)* years for which complete data are available for the facility or agency. The fiscal year begins in January (Month).

	Year 2013	Year 2014	Year 2015
A. Utilization Data (Specify unit of measure) Adjusted Patient Days	719,580	741,515	760,677
B. Revenue from Services to Patients		(in thousands)	
1. Inpatient Services	$ 2,699,155	$ 2,754,329	$ 2,999,684
2. Outpatient Services	2,476,668	2,826,784	2,970,661
3. Emergency Services	313,851	366,834	378,666
4. Other Operating Revenue (Attachment C: Historical Chart)	77,123	100,345	136,301
Gross Operating Revenue	**$ 5,566,797**	**$ 6,048,292**	**$ 6,485,312**
C. Deductions from Gross Operating Revenue			
1. Contractual Adjustments	$ 3,485,935	$ 3,848,401	$ 4,103,811
2. Provision for Charity Care	348,997	377,105	361,519
3. Provisions for Bad Debt	154,172	155,627	163,510
Total Deductions	**$ 3,989,104**	**$ 4,381,133**	**$ 4,628,840**
NET OPERATING REVENUE	**$ 1,577,693**	**1,667,159**	**1,856,472**
Operating Expenses			
1. Salaries and Wages	$ 575,773	$ 596,539	$ 659,660
2. Physician's Salaries and Wages	41,322	66,862	51,219
3. Supplies	335,111	340,428	384,238
4. Taxes	1,715	2,179	2,224
5. Depreciation	89,112	102,845	106,017
6. Rent	15,494	17,432	17,211
7. Interest, other than Capital			
8. Management Fees a) Fees to Affiliates	3,329	3,852	3,784
b) Fees to Non-Affiliates	4,461	4,570	4,389
9. Other Expenses (Attachment C: Historical Chart)	433,434	449,956	492,005
Total Operating Expenses	**$ 1,499,751**	**$ 1,584,663**	**$ 1,720,747**
E. Other Revenue (Expenses) – Net	$ 255,431	$ (54,069)	$ 34,163
NET OPERATING INCOME (LOSS)	**$ 333,373**	**28,427**	**169,888**
F. Capital Expenditures			
1. Retirement of Principal	$ -	$ -	$ -
2. Interest	25,874	26,798	25,489
Total Capital Expenditures	**$ 25,874**	**$ 26,798**	**$ 25,489**
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	**$ 307,499**	**1,629**	**144,399**

PROJECTED DATA CHART

Methodist Healthcare-University Hospital

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

			Year 2019	Year 2020
A.	Utilization Data (Adjusted Patient Days)		223,139	223,110
B.	Revenue from Services to Patients		(in thousands)	
	1. Inpatient Services		$ 1,281,950	$ 1,343,456
	2. Outpatient Services		879,220	928,057
	3. Emergency Services		80,328	85,041
	4. Other Operating Revenue (Attachment C: Projected Chart)		60,428	61,247
	Gross Operating Revenue		**$ 2,301,926**	**$ 2,417,801**
C.	Deductions from Gross Operating Revenue			
	1. Contractual Adjustments		$ 1,521,388	$ 1,610,084
	2. Provision for Charity Care		187,826	195,555
	3. Provisions for Bad Debt		40,749	42,409
	Total Deductions		**$ 1,749,963**	**$ 1,848,048**
NET OPERATING REVENUE			**$ 551,963**	**569,752**
D.	Operating Expenses			
	1. Salaries and Wages		$ 151,728	$ 154,935
	2. Physician's Salaries and Wages		3,741	3,819
	3. Supplies		180,175	187,499
	4. Taxes		96	96
	5. Depreciation		43,441	43,099
	6. Rent		-	-
	7. Interest, other than Capital		-	-
	8. Management Fees	a.) Fees to Affiliates	1,009	1,029
		a.) Fees to Non-Affiliates	-	-
	8. Other Expenses	(Attachment C: Projected Chart)	186,007	191,576
	Total Operating Expenses		**$ 566,197**	**$ 582,052**
E.	Other Revenue (Expenses) -- Net		$ 6,395	$ 6,681
NET OPERATING INCOME (LOSS)			**$ (7,839)**	**$ (5,618)**
F.	Capital Expenditures			
	1. Retirement of Principal		-	-
	2. Interest		1,724	1,644
	Total Capital Expenditures		**$ 1,724**	**$ 1,644**
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES			**$ (9,563)**	**$ (7,262)**

6. **A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.**

There will be no change to the existing room and bed charge structure as a result of this project, yet there will be normal unrelated rate increases over the next several years. See the current charges below.

Charge/Procedure	Current Rate
ROOM AND BED	
MED-SURG PRIVATE R&B	$ 1,399
PYSCH PRIVATE R&B	$ 1,147
PYSCH SEMI-PRIVATE R&B	$ 1,117
ICU/CCU R&B	$ 2,492
CVICU -R&B	$ 2,933

B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projected recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

Based upon the review, the proposed charges are reasonable and comparable to other facilities in the service area. There will be no impact to the charge structure due to this project. The table below shows the comparison of charges based on data from the Federal Fiscal yearend 2014 American Hospital Directory (AHD) for area hospitals.

METHODIST SERVICE AREA
CHARGE COMPARISON

Facility	Average Gross Charge	Average Payment
Methodist University	$44,043	$12,695
Baptist Memorial Memphis	$53,589	$12,363
St. Francis Memphis	$77,778	$11,444
St. Francis Bartlett	$63,320	$9,313
Regional One	$101,286	$30,685
Source: American Hospital Directory - Medicare IPPS claims data are for federal fiscal year ending 09/30/2014 – Inpatient Utilization Statistics		

7. **Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.**

The proposed project will improve operational efficiency on the Methodist University campus. Methodist Le Bonheur Healthcare will remain financially viable.

The most successful healthcare organizations must not only deliver high-quality care, but also do so with minimum waste. Cost controls are increasingly part of the quality conversation in healthcare, and the systematic identification and elimination of waste while maintaining or improving quality is imperative for

future success. Methodist Le Bonheur Healthcare remains committed to providing sustainable, high-quality care. To do so going forward, we are compelled to focus on enhancing the entire experience of care for patients, while managing the costs of delivering that care.

8. **Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.**

   All cash is held at the corporate level, see the attached Methodist Le Bonheur Healthcare December 2015 Balance Sheet (Attachment C: Economic Feasibility (10)) for the financial viability of the health system. The projections in this application show the system will remain viable although there are moderate losses in the first years of operation as a result of additional depreciation. Methodist University Hospital is an integral part of Methodist Healthcare-Memphis Hospitals with 617 of the total 1,583 licensed beds. As the system's flagship academic medical center, this investment is essential for long term viability and sustainability of the campus and system.

9. **Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.**

   Methodist University Hospital currently serves the Medicare, TennCare, and medically indigent populations. The estimated payer mix for 2019, the first full year of operation, is shown below.

Payor	Revenue (In Thousands)	% of Total Revenue
Medicare	$ 1,109,105	49%
TennCare/Medicaid	$ 311,280	14%
Self-Pay	$231,762	10%
Commercial/Other	$ 589,352	26%
Total	$2,241,498	100%

10. **Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-10.**

    Audited financials and cash are held at the corporate level, therefore, please see the attached most recent audited financials for Methodist Healthcare. Also, a balance sheet and income statement for the period ending December 31, 2015 for Methodist Le Bonheur Healthcare are included. See Attachment C: Economic Feasibility (10).

11. **Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:**

    a. **A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.**

b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

Response to a. and b. above:

Methodist Healthcare evaluated the health care services, community benefits, and cost effectiveness of construction alternatives during the planning of the project. One option was to renovate existing patient care floors and support areas. The age and condition of the existing hospital buildings are not optimal for in-place renovations. As previously mentioned in the application, the outdated buildings present renovation challenges with the spacing and the floor-to-ceiling heights for twenty-first century healthcare and technology.

DIAGRAM 5
METHODIST UNIVERSITY HOSPITAL
COLOR CODED BUILDING CONDITION ASSESSMENT RESULTS

Additionally, Methodist University's presence in high priority programs requires improving adjacencies and addressing inadequate and inefficient space and equipment, both on the inpatient and outpatient side. This alternative could not solve those problems with existing buildings. The campus plan assessment reveals the most viable option is to renovate and modernize the facility as proposed in this application.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. **List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.**

   Methodist Healthcare has working relationships with the following physician groups:
   - The West Clinic
   - UT Medical Group, Inc.
   - UT Le Bonheur Pediatric Specialists
   - Campbell Clinic Orthopaedics
   - Pediatric Anesthesiologists PA
   - Pediatric Emergency Specialists PC
   - Semmes-Murphey Neurologic and Spine Institute
   - Methodist Primary and Specialty Care Groups (See Attachment A:4 for Organizational Chart)

   The Methodist Healthcare-Memphis Hospitals' license includes five hospitals:
   - Methodist Healthcare-University Hospital
   - Methodist Healthcare-South Hospital
   - Methodist Healthcare-North Hospital
   - Methodist Healthcare-Le Bonheur Germantown Hospital
   - Le Bonheur Children's Hospital

   Additionally, Methodist Healthcare owns and operates Methodist Alliance Services, a comprehensive home care company, and a wide array of other ambulatory services such as minor medical and urgent care centers, outpatient diagnostic centers and ambulatory surgery centers.

   Methodist Healthcare is part of the University Medical Center Alliance which also includes the University of Tennessee and the Memphis Regional Medical Center (The Med). The goal of this council is to support the quality of care, patient safety and efficiency across all three institutions.

   There are also agreements with the Mid-South Tissue Bank, the Mid-South Transplant Foundation, and PhyAmerica.

   A list of managed care contracts is attached in Attachment C: Orderly Development (1).

2. **Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.**

   The proposed project will have a positive impact on the Shelby County health care community. The project does not propose to increase the applicant's market share. The project is for renovation and modernization to the campus to improve patient flow, efficiencies, and patient satisfaction.

3. **Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.**

   The project will not require the addition of FTEs. There will be no change in staffing patterns.

4. **Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.**

   The project will not require the addition of FTEs. There will be no change in staffing patterns.

5. **Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review *policies and programs, record keeping, and staff education.***

   The applicant so verifies. Methodist University Hospital reviewed and meets all the State requirements for physician supervision, credentialing, admission privileges, and quality assurance policies and programs, utilization review policies and programs, record keeping and staff education.

6. **Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (*e.g.*, internships, residencies, etc.).**

   Methodist Healthcare has clinical affiliation agreements with multiple colleges including over twenty for nursing, thirty for rehabilitation service professionals (physical therapy, speech therapy, and audiology), three for pharmacy, and almost twenty for other allied health professionals including paramedics, laboratory, respiratory therapy, radiation therapy technicians. There are approximately 1400 students annually participating in these programs.

   Methodist participates very heavily in the training of students from various medical disciplines. Since relationships exist with most of the schools in Memphis, most of the students have also been trained academically in this region. The three primary disciplines that participate in the training of students at Methodist are medicine, nursing and psychosocial services.

   In the area of medicine, there are many different specialties represented in the interns and residents who train at Methodist – there are more than twenty different specialties. Likewise, since there are several nursing schools in the area, Methodist is very active in the training of future nurses. These nurses come from several types of programs, which include Bachelor's Degrees, Associate Degrees, Licensed Practical Nurse programs and Diploma programs. Methodist participates in training of students from the following schools:

   Methodist Healthcare
   University of Memphis
   Baptist Health System
   Southwest Tennessee Community College
   University of Tennessee
   Northwest Mississippi Jr. College
   Regional Medical Center
   Tennessee Centers of Technology

7. **(a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.**

   Methodist University Hospital has reviewed these, and meets all applicable requirements of the Department of Health. Other departments are not involved with this facility.

   (b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

Licensure:

The general hospital license held by Methodist Healthcare-Memphis Hospitals d/b/a Methodist University Hospital is from the Tennessee Department of Health, Board for Licensing Health Care Facilities.

Accreditation:

The accreditation agency for Methodist University Hospital is the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), from whom the hospital has full accreditation.

(c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.

Methodist University Hospital is in good standing with the Department of Health, the Healthcare Facility Licensing Board, and JCAHO. (See Attachment C: Orderly Development (7)(c))

(d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.

Documentation regarding deficiencies and approved plan of correction in our licensure is attached. See Attachment C: Orderly Development (7)(d)(1) and C: Orderly Development (7)(d)(2).

8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.

None

9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project.

None

10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

Should this application be approved, Methodist University Hospital will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper as proof of the publication of the letter of intent.

The full page of the Commercial Appeal newspaper in which the Notice of Intent appeared is attached as Attachment C: Proof of Publication.

DEVELOPMENT SCHEDULE

Tennessee Code Annotated § 68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

1. **Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.**

   See the Project Completion Forecast Chart on the following page. The applicant anticipates that the project will be fully completed by November 2019 which is beyond the standard time allowed, i.e. three years from the date of receiving the CON. There will be three phases of this project. The first includes the new construction of the patient tower and ambulatory building. This phase is proposed to be complete by December 2018 with the newly constructed beds and services in operation January 2019. The further renovation of the existing buildings will not be complete until May 2019 and the demolition will not be complete until November 2019.

2. **If the response to the preceding question *indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph,* please state below any request for an extended schedule and document the "good cause" for such an extension.**

   As noted above the construction of the new patient tower and ambulatory building as well as the renovations of existing buildings is scheduled to be complete by May 2019 which would fall within the three year timeframe, yet the demolition and final phases will continue through the end of the year.

   The extended schedule is in part due to the following:

   - The new patient tower spans an active road
   - The new patient tower will connect to existing facilities at several locations
   - The site is not a greenfield site yet is an onsite modernization project in a busy campus

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as published in T.C.A. § 68 –11-1609(c): June 2016

Assuming the CON approval becomes the final agency action on that date; indicate the number of days **from the above agency decision date** to each phase of the completion forecast.

Phase	**DAYS REQUIRED**	**Anticipated Date (MONTH/YEAR)**
1. Architectural and engineering contract signed	-	June 2016
2. Construction documents approved by the Tennessee Department of Health	180	November 2016
3. Construction contract signed	180	November 2016
4. Building permit secured	180	November 2016
5. Site preparation completed	210	December 2016
6. Building construction commenced	210	December 2016
7. Construction 40% complete	470	September 2017
8. Construction 80% complete	810	August 2018
9. Construction 100% complete (approved for occupancy)	New 930 Renov 1080 Demo 1260	December 2018 May 2019 November 2019
10. *Issuance of license	New 960	January 2019
11. *Initiation of service	New 960	January 2019
12. Final Architectural Certification of Payment	1320	January 2020
13. Final Project Report Form (HF0055)	1350	February 2020

* **For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.**

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final

ATTACHMENTS

INDEX OF ATTACHMENTS

A:3	Corporate Charter and Certificate of Existence
A:4	Ownership-Legal Entity and Organization Chart
A:6	Site Control
B:II (E)(3)	Vendor Quotes
B:II (E)(4)	FDA Approvals
B:III (A)	Plot Plan
B:III (B)	Road Maps and Public Transportation Routes
B:IV	Floor Plans
C: Need (3)	Service Area Maps
C: Need PET Criteria (6)(d)	Physician Order Policy
C: Need PET Criteria (6)(e)(1)	Medical Director CV
C: Need PET Criteria (6)(e)(2)	Medical Director's Scope of Responsibilities
C: Economic Feasibility (1)(d)	Documentation of Construction Cost Estimate
C: Economic Feasibility Project Costs Chart	Equipment Listing Over $50,000
C: Economic Feasibility (2)	Documentation of Availability of Funding
C: Economic Feasibility Historical Chart	Other Revenue and Expense Listing
C: Economic Feasibility Projected Chart	Other Revenue and Expense Detail
C: Economic Feasibility (10)	Financial Statements
C: Orderly Development (1)	List of Managed Care Contracts
C: Orderly Development (6)	List of Clinical Affiliations
C: Orderly Development (7)(c)	License from Board of Licensing Health Care Facilities
C: Orderly Development (7)(d)(1)	TDH Licensure Survey and Plan of Correction
C: Orderly Development (7)(d)(2)	JCAHO Accreditation and Survey Summary
C: Proof of Publication	Proof of Publication

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A: 3 Corporate Charter and Certificate of Existence

ARTICLES OF AMENDMENT TO THE CHARTER

OF

METHODIST HOSPITALS OF MEMPHIS

Pursuant to the provisions of Section 48-60-101 et. seq. of the Tennessee Nonprofit Corporation Act, the undersigned corporation adopts the following Articles of Amendment to its Charter:

1. The name of the corporation is:

   Methodist Hospitals of Memphis

2. The amendment adopted is:

   The name of the corporation is hereby changed from Methodist Hospitals of Memphis to Methodist Healthcare - Memphis Hospitals.

3. The Amendment was duly adopted on January 15, 1998 by the Board of Directors of Methodist Health Systems, Inc., a Tennessee nonprofit corporation, acting as the Members of Methodist Hospitals of Memphis.

4. This amendment shall be effective February 1, 1998.

5. Additional approval for this charter amendment was not required.

DATED this 27th day of January 1998 at Memphis, Tennessee.

SIGNED BY:

W. Steven West
General Counsel/Assistant Secretary

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AMENDED AND RESTATED CHARTER
OF
METHODIST HOSPITALS OF MEMPHIS

HG 7448

Pursuant to the provisions of § 48-1-304 of the Tennessee General Corporation Act, Methodist Hospitals of Memphis adopts the following restated charter:

PART I

1. The name of the Corporation is:

METHODIST HOSPITALS OF MEMPHIS

2. The duration of the Corporation is perpetual.

3. The address of the principal office of the Corporation in the State of Tennessee shall be 1265 Union Avenue, Memphis, Shelby County, Tennessee.

4. The Corporation is not for profit.

5. The purposes for which the Corporation is organized are:

a. To respond to the love of God by continuing the ministry of healing in the spirit of Jesus Christ.

b. This Corporation is organized and shall be operated exclusively for charitable, scientific, literary, religious and educational purposes; no part of the net earnings of the Corporation shall inure to the benefit of any individual; no substantial part of the activities shall be the carrying on of propaganda, or otherwise attempting to influence legislation; and the Corporation shall not participate in, or intervene in (including the publishing or distribution of statements) any political campaign on behalf of any candidate for public office.

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c. To establish, purchase, own, operate, support, lease, manage, conduct or maintain one or more hospitals, institutions, nursing homes, convalescent centers, ambulance services or other facilities and services for the care and treatment of the injured, sick, diseased, disabled, afflicted, aged and infirm; and to support the business, activities and programs of and to aid, assist and confer benefits upon Methodist Health Systems, Inc., a Tennessee not for profit corporation which is an exempt organization described in Sections 501(c)(3) and 170(c)(2) of the Internal Revenue Code of 1954, as amended, or any of its affiliated organizations, all within or outside the State of Tennessee.

d. To provide, operate, support, conduct or promote any educational, scientific or research activities related to health care.

e. To establish, join, cooperate or engage in joint ventures, associations, groups or cooperatives with other hospitals, health care providers, individuals, corporations, or any other entity, including, but not limited to, Methodist Health Systems, Inc. or any of its affiliated organizations, to advance or promote the general health of communities within or outside the State of Tennessee or to advance or promote the efficient delivery of health care within or outside the State of Tennessee.

f. To make loans, grants, awards, prizes and scholarships; to share its services, equipment and property with others; to assist and cooperate with other hospitals and others; and to engage in any other activities designed to advance or promote the efficient delivery of health care, or to advance or promote the general health of communities within or outside the State of Tennessee.

g. To manufacture, fabricate, assemble, distribute, warehouse, sell and deal in any products, goods, equipment or other property for use by this corporation or others in the rendering of health care or to promote or advance the general health of communities within or outside the State of Tennessee.

h. To engage in any activities which are appropriate to carry out and fulfill any or all of the foregoing purposes, including, without limitation, for such purposes, the making of payments, loans, distributions and guaranties, the pooling of credit, assumption of joint and several obligations and the sharing of funds, assets and proceeds of financing with Methodist Health Systems, Inc., a Tennessee not for profit corporation, or any of its affiliated organizations.

i. To have and exercise all the powers as are permitted by the Tennessee General Corporation Act.

j. Notwithstanding any other provision of these articles, this Corporation shall not carry on any activity not permitted to be carried on by (a) a corporation exempt from Federal Income Tax under Section 501(c)(3) of the Internal Revenue Code of 1954 or the corresponding provisions of any future United States Internal Revenue Law or (b) a corporation, contributions to which are deductible under Section 170(c)(2) of the Internal Revenue Code of 1954 or or the corresponding provision of any future United States Internal Revenue Law.

6. This Corporation shall have as its members those persons who are from time to time the members of the Board of Directors of Methodist Health Systems, Inc., a Tennessee not for profit corporation, or any successor thereto, which is an

exempt organization described in Sections 501(c)(3) and 509(a)(2) of the Internal Revenue Code of 1954, as amended.

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7. The governing body of this Corporation shall be a Board of Directors who shall manage its business and affairs. The directors shall be of legal age and need not be residents of the State of Tennessee. The number of directors and their terms of office shall be fixed and determined by the by-laws; except that, there shall not be less than three directors. The directors shall be elected by the members and may be removed by the members at any time, with or without cause.

8. A majority of the directors then in office shall constitute a quorum at any meeting of the directors.

9. The charter and by-laws of this Corporation may be altered, amended or repealed by the members subject to prior written approval of Methodist Health Systems, Inc. and such approval may be executed by any president or vice president thereof.

10. This Corporation may be merged, consolidated or dissolved only by action of the members.

11. Any action required or permitted to be taken at a meeting of the Board of Directors or any Board Committee may be taken without a meeting if consent in writing, setting forth the action so taken, is signed by all of the members of the Board of Directors or Board Committee as the case may be.

12. In the event of dissolution, the residual assets of this Corporation shall be turned over to Methodist Health Systems, Inc., a Tennessee not for profit corporation, or any other organization or organizations which are "restricted affiliates" (as hereinafter defined); provided, however, no part of the residual assets of the Corporation shall be turned

thereof to any such organization unless such organization is itself an exempt organization described in Sections 501(c)(3) and 170(c)(2) of the Internal Revenue Code of 1954, as amended (or corresponding sections of any prior or future Internal Revenue Code). If neither Methodist Health Systems, Inc. nor any such restricted affiliate is such an exempt organization, then the residual assets of the Corporation shall be turned over to one or more other organizations which at that time are organizations described in Section 501(c)(3) and 170(c)(2) and in exempt from federal income taxes under Section 501(a) and is not a "private foundation" within the meaning of Section 509(a) of the Internal Revenue Code of 1954, as amended (or corresponding sections of any prior or future Internal Revenue Code), or to any federal, state or local government for exclusively public purposes. As used herein, "restricted affiliate" shall have the meaning of such term as utilized in any master trust indenture or other similar financing agreement to which the Corporation or Methodist Health Systems, Inc. is a party and which is in effect at the time of dissolution.

PART II

1. The date the original Charter was filed by the Secretary of State was August 1, 1922.

2. The Amended and Restated Charter restates the text of the Charter, as previously amended, and further amends the charter as specified below, and was duly adopted at a meeting of the member on June 12, 1985:

(a) Paragraphs 5(b), 5(c), 5(e), 5(h), 6, 7, 8, 9, 10 and 11 of the Charter, as previously amended, have been deleted in their entirety, with the foregoing paragraphs 5(b), 5(c), 5(e), 5(h), 6, 7, 8, 9, 10 and 11, respectively, being substituted therefor.

(b) The foregoing paragraph 12 has been added to the Charter.

W6 7448

The foregoing restated charter was adopted at a meeting of the members on June 12, 1985.

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The foregoing restated charter is to be effective when these articles of amendment are filed by the Secretary of State of Tennessee.

DATED this 17th day of June, 1985.

METHODIST HOSPITALS OF MEMPHIS

By: Judge J. Catton
President

W6 7448

STATE TAX _____
REGISTER'S FEE 5.00
RECORDING FEE _____
Jul 11 4 01 PM '85
STATE OF TENNESSEE
SHELBY COUNTY
REGISTER

5.00

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ARTICLES OF AMENDMENT

TO THE CHARTER

OF

METHODIST HOSPITALS OF MEMPHIS

Pursuant to the provisions of Section 48-303 of the Tennessee General Corporation Act, the undersigned Corporation adopts the following Articles of Amendment to its Charter:

1. The name of the Corporation is:

METHODIST HOSPITALS OF MEMPHIS

2. The Amendment adopted is: paragraphs (6), (8), (9), (10) and (11) of the Articles of Amendment to the Charter filed with the Secretary of State, State of Tennessee on October 7, 1981, are deleted and the following are substituted therefor:

(6) This Corporation shall have as its sole member Methodist Health Systems, Inc., a Tennessee not-for-profit corporation.

(8) The governing body of this Corporation shall be a Board of Directors who shall manage its business and affairs. The Directors shall be of legal age and need not be residents of the State of Tennessee. The number of Directors and the term of their office shall be fixed and determined by the By-laws; except that, there shall not be less than three (3) Directors. The Directors shall be elected by the member.

(9) By-laws of this Corporation shall be adopted, amended or repealed by the member.

(10) This Corporation may be dissolved or its Charter amended only by action of the member.

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(11) A majority of the Directors then in office shall constitute a quorum at any meeting of the Directors.

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3. This Amendment was duly adopted at a meeting of the members on June 23, 1982.

4. The foregoing Amendment is to be effective when these Articles of Amendment are filed by the Secretary of State, State of Tennessee.

DATED June 23, 1982.

METHODIST HOSPITALS OF MEMPHIS

By: Judge D. Calton
President

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ARTICLES OF AMENDMENT TO THE CHARTER
OF
METHODIST HOSPITAL

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58 5818

Under the authority of Section 48-303 of the Tennessee General Corporation Act, Methodist Hospital amends its charter as follows:

All of the provisions of the Charter are hereby deleted and the following substituted therefor:

(1) The name of the corporation is Methodist Hospitals of Memphis.

(2) The duration of the corporation is perpetual.

(3) The address of the principal office of the corporation in the State of Tennessee shall be 1265 Union Avenue, Memphis, Shelby County, Tennessee.

(4) The corporation is not for profit.

(5) The purposes for which the corporation is organized are:

a. To respond to the love of God by continuing the ministry of healing in the spirit of Jesus Christ.

b. This corporation is organized and shall be operated exclusively for charitable, scientific, literary, religious and educational purposes; no part of the earnings shall inure to the benefit of any individual; no substantial part of the activities shall carry on propoganda, or otherwise attempt to influence legislation, and the corporation shall not participate in, or intervene in (including the

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publishing or distributing of statements), any
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SB 5218

c. To establish, own, operate, support, lease, manage, conduct and/or maintain one or more hospitals, institutions, homes, and/or other facilities within and/or outside the State of Tennessee for the care and treatment of the injured, sick, diseased, disabled, afflicted, aged and infirm.

d. To provide, operate, support, conduct and/or promote any educational, scientific and/or research activities related to health care.

e. To establish, join, cooperate and/or engage in joint ventures, associations, groups and/or cooperatives with other hospitals, health care providers, individuals, corporations, or any other entity to advance or promote the general health of communities within and outside the State of Tennessee, or to advance or promote the efficient delivery of health care.

f. To make loans, grants, awards, prizes and scholarships; to share its services, equipment and property with others; to assist and cooperate with other hospitals and others; and to engage in any other activities designed to advance or promote the efficient delivery of health care, or to advance or promote the general health of communities within and outside the State of Tennessee.

g. To manufacture, fabricate, assemble, distribute, warehouse, sell and deal in any products, goods, equipment or other property for use by this corporation and/or others in the rendering of

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health care or to promote or advance the general health of the communities within and outside the State of Tennessee.

b. To engage in any activities which are appropriate to carry out and fulfill any or all of the foregoing purposes.

i. To have and exercise all of the powers as are permitted by the Tennessee General Corporation Act.

j. Notwithstanding any other provision of these articles, this corporation shall not carry on any activity not permitted to be carried on by (a) a corporation exempt from Federal Income Tax under Section 501(c)(3) of the Internal Revenue Code of 1954 or the corresponding provision of any future United States Internal Revenue Law or (b) a corporation, contributions to which are deductible under Section 170(c)(2) of the Internal Revenue Code of 1954 or any other corresponding provision of any future United States Internal Revenue Law.

(6) This corporation is to have members who shall be called Trustees. The Memphis, North Mississippi, and North Arkansas Annual Conferences of the United Methodist Church each shall elect six Trustees, four of whom shall be lay persons and two of whom shall be ordained United Methodist ministers. The by-laws of Methodist Hospitals of Memphis shall provide for the length of the term of Trustees and for the filling of any vacancies. A Trustee may be removed from office for any reason by the Annual Conference that elected the Trustee.

(7) In the event of dissolution, the residual assets of the organization will be turned over to one or more organizations which themselves are exempt as organizations described in Sections 501(c)(3) and 170(c)(2) of the

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Internal Revenue Code of 1954 or corresponding sections of any [illegible] Internal Revenue Code, or [illegible] Federal, State, or local government for exclusive public purposes.

58 5216

(8) The governing body of this corporation shall be a Board of Directors who shall manage its business and affairs. The directors shall be of legal age and need not be residents of the State of Tennessee. The number of directors and the term of their office shall be fixed and determined by the by-laws; except that, there shall not be less than three directors. The Trustees shall elect the directors.

(9) By-laws of this corporation shall be adopted, amended or repealed by the Board of Trustees by such vote as may be therein specified.

(10) This corporation may be dissolved or its Charter amended only by action of the Trustees.

(11) A majority of the Trustees shall constitute a quorum at any meeting of the Trustees. A majority of the Directors then in office shall constitute a quorum at any meeting of the Directors.

3. The amendment was duly adopted by the unanimous written consent of the members on June 8, 1981.

4. The amendment is to be effective when these articles of amendment are filed by the Secretary of State, State of Tennessee.

Dated September 23, 1981.

METHODIST HOSPITAL

By: [signature] President

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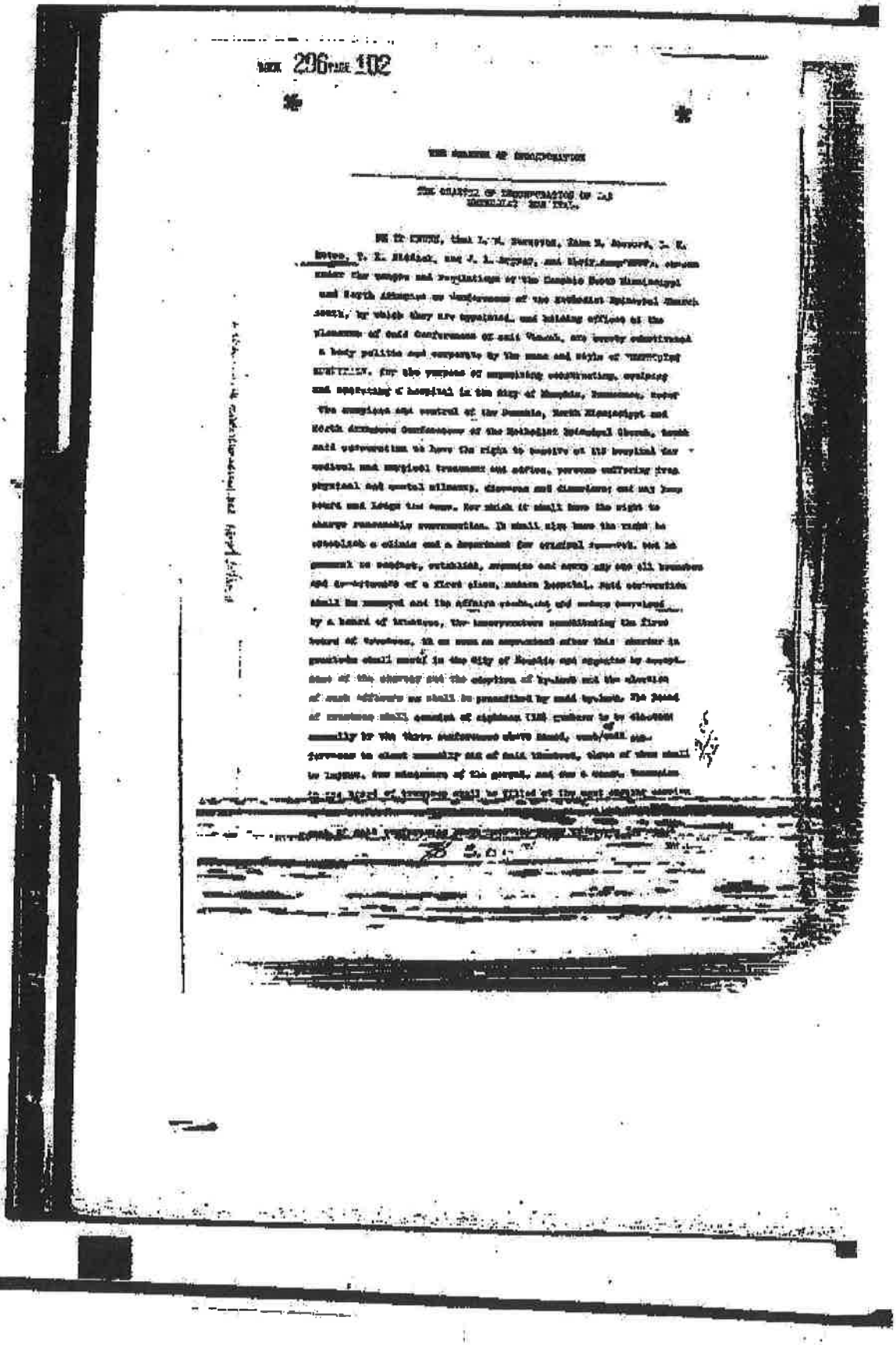


BOOK 296 PAGE 102

THE CHARTER OF INCORPORATION

THE CHARTER OF INCORPORATION OF [redacted]
MEMPHIS, SHELBY COUNTY, TENNESSEE

BE IT KNOWN, that [redacted], [redacted], [redacted], [redacted], and [redacted], citizens under the counties and jurisdictions of the Memphis Annual Conference and North Mississippi Conference of the Methodist Episcopal Church, South, by which they are appointed, and holding offices on the Missionary Board of said Conferences of said Church, are hereby constituted a body politic and corporate by the name and style of "[redacted]" for the purpose of organizing, establishing, erecting and operating a hospital in the city of Memphis, Tennessee, under the auspices and control of the Memphis, North Mississippi and North Arkansas Conferences of the Methodist Episcopal Church, South and said corporation to have the right to receive at its hospital for medical and surgical treatment such sick, persons suffering from physical and mental ailments, diseases and disorders; and may have power and lodge the same. For which it shall have the right to charge reasonable compensation. It shall also have the right to establish a clinic and a department for criminal research, but is granted to construct, establish, maintain and carry on any and all branches and departments of a first class, modern hospital. Said corporation shall be managed and its affairs [redacted] and business conducted by a board of trustees, the incorporators constituting the first board of trustees, to be known as corporators after this charter is granted; shall meet in the city of Memphis and organize by electing one of the charter and the adoption of by-laws and the election of such officers as shall be prescribed by said by-laws. The board of trustees shall consist of eighteen (18) members to be elected annually by the three conferences above named, each [redacted] conference to elect annually six of said trustees, three of whom shall be laymen, four ministers of the gospel, and one a woman. Vacancies in the board of trustees shall be filled at the next regular session

any member of said board or trustee or the representative of said corporation, after giving said trustee or trustees opportunity to be heard in his own behalf, said corporation may designate a committee or agency and invest it with power to fill vacancies for and on behalf of the trustee or the trustees of said corporation, said board of trustees shall have the power to elect a board of managers of the said hospital and to adopt all by laws, rules and regulations for the proper operation of the corporation as may be necessary for the proper conduct of the ministry.

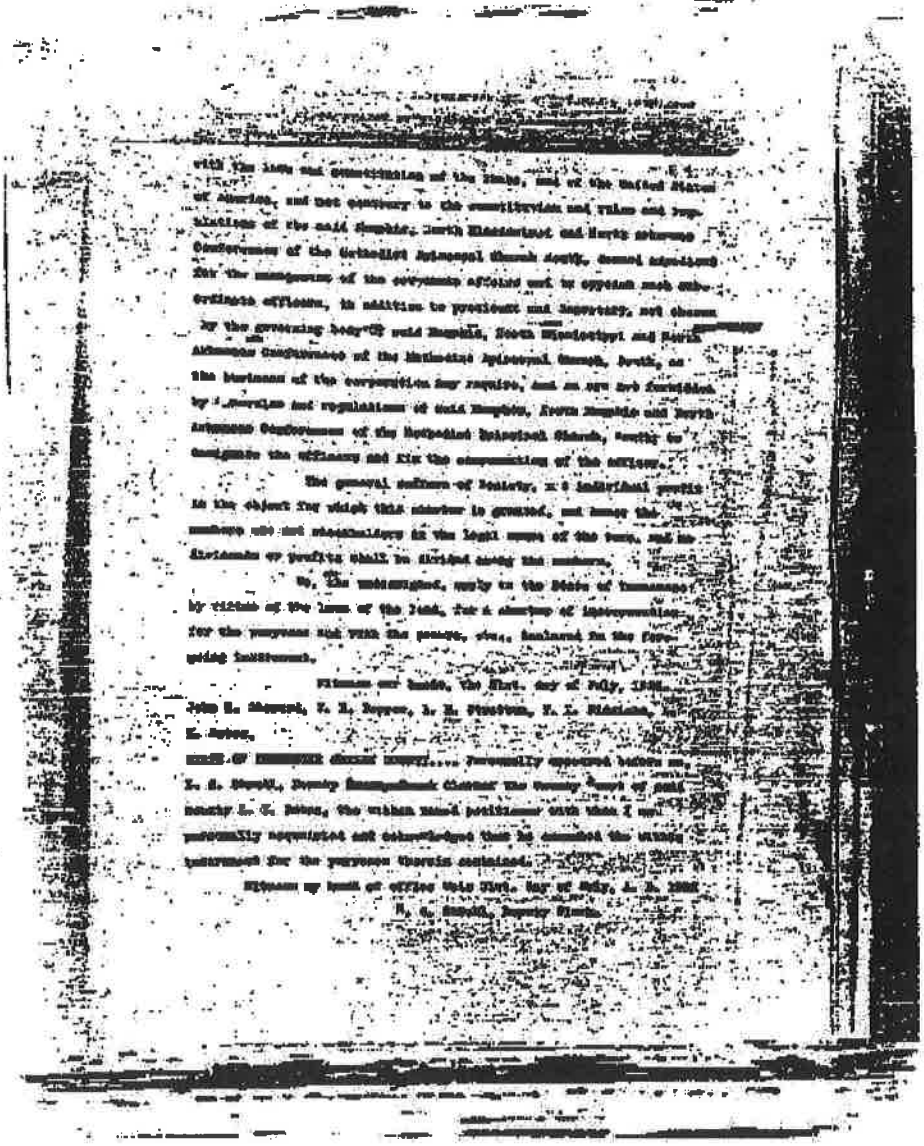
The said corporation, and the hospital as established shall be subject to the visitorial power of the said annual conference of the Methodist Episcopal Church, South.

And be it known that, said corporation may purchase, own or lease land for corporate purposes, erect suitable plant buildings for the carrying on of the business of the corporation and make title to any real estate or other property owned by the corporation; employ all necessary agents for the transaction of the business of the corporation as solicitors, collectors, and receive subscriptions in money and otherwise, invested or loaned as may be in field of investment may and all of the purposes of the corporation aforesaid or and all necessary printing printed, typed, and material for the purpose of carrying on the work of the corporation.

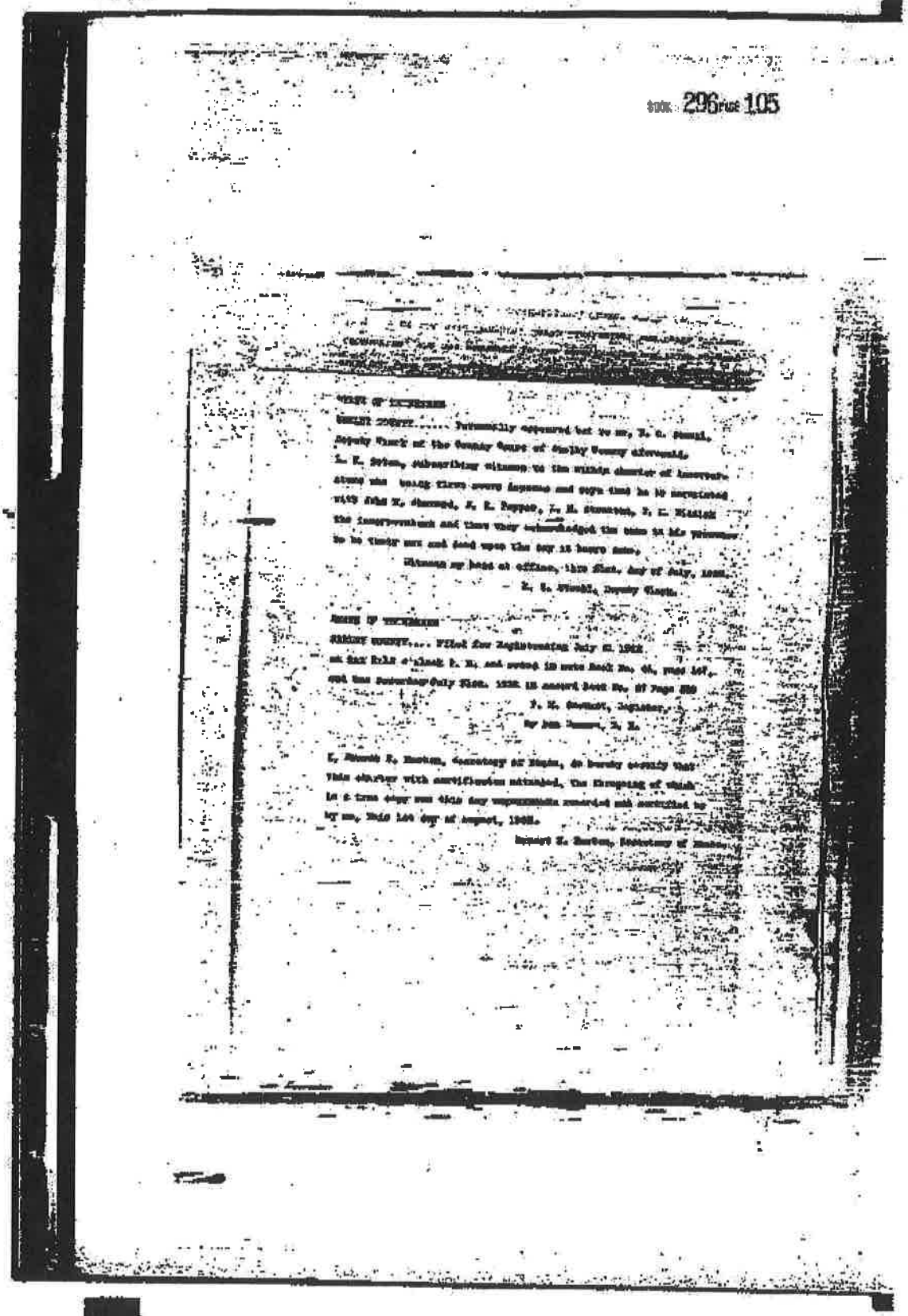
And in all transactions of the said corporation is to be governed by the rules and regulations of the said Augusta South Mississippi and North Arkansas Conferences of the Methodist Episcopal Church, South, insofar as the same are consistent with the constitution of the State and the laws of the land.

The general powers of said corporation shall be to sue and to be sued of the corporate name; to have and use a common seal, which it may alter at pleasure; if it has no common seal, then the signature of any duly authorized officer shall be legal and binding. To purchase and hold, or receive by gift, devise, or bequest in addition to the personal property owned by the corporation, real estate necessary for the transaction of the corporate business and also to purchase and accept any sum coming to the corporation [illegible]

BOOK 296 PAGE 104



Book 296 Page 105



STATE OF TENNESSEE

CHARTER OF INCORPORATION

THE CHARTER OF INCORPORATION OF THE

METHODIST HOSPITAL

BE IT KNOWN, That L.M.STRATTON, JOHN H. SHERARD, L. H. ESTES, T. K. RIDDICK, and J. R. PEPPER, and their successors, chosen under the usages and regulations of the Memphis, North Arkansas and North Mississippi Conferences of the Methodist Episcopal Church, South, by which they are appointed, and holding offices at the pleasure of said Conferences of said Church, are hereby constituted a body politic and corporate by the name and style of "METHODIST HOSPITAL" for the purpose of organizing, constructing, equipping and operating a hospital in the city of Memphis, Tennessee, under auspices and control of the Memphis, North Arkansas and North Mississippi Conferences of the Methodist Episcopal Church, South; said corporation to have the right to receive at its hospital for medical and surgical treatment and advice, persons suffering from physical and mental ailments, diseases and disorders; and may keep, board and lodge the same, for which it shall have the right to charge reasonable compensation. It shall also have the right to establish a clinic and a department for original research, and in general to conduct, establish, organize and equip any and all branches and departments of a first class, modern hospital. Said corporation shall be managed and its affairs conducted and powers exercised by a Board of Trustees, the incorporators constituting the first Board of Trustees, who as soon as convenient after this Charter is granted, shall meet in the City of Memphis and organize by acceptance of the Charter and the adoption of by-laws and the election of such officers as shall be prescribed by said by-laws. The Board of Trustees shall consist of eighteen (18) members to be elected annually by the three conferences above named, each of said conferences to elect annually six of said trustees, three of whom shall be laymen, two ministers of the gospel, and one a woman. Vacancies in the Board of Trustees shall be filled at the next ensuing session of the Conference in whose representation such vacancy occurs, and each of said conferences shall have the power to remove for cause any member of said board so chosen as the representative of said conference, after giving said trustee an opportunity to be heard in his own defense. Said conferences may designate a committee or agency and invest it with power to fill vacancies for and on its behalf in the interim of the sessions of said conferences. Said Board of Trustees shall have the power to elect a Board of Managers of the said Hospital and to adopt all by-laws, rules and regulations for the administration of the said Hospital as may be necessary for the proper conduct of its affairs.

The said corporation, and the hospital so established, shall be subject to the visitorial powers of the said Annual Conferences of the Methodist Episcopal Church, South.

And to these ends, said corporation may purchase, own or lease land for corporate purposes, borrow money when necessary for the carrying on of the business of the corporation; sell and make title to any real estate or other property owned by the corporation; employ all necessary agents for the transaction of the business of the corporation; to solicit, collect, and receive subscriptions in money and otherwise, legacies or devises to be used

in aid of forwarding any and all of the purposes of the corporation; purchase or rent all necessary printing presses, type, and material for the far as the same are not inconsistent with the constitution of the state and the laws of the land.

The general powers of said corporation shall be to sue and be sued by the corporate name; to have and to use a common seal, which it may alter at pleasure; if it has no common seal, then the signature of any duly author ized officer shall be legal and binding. To purchase and hold or receive by gift, devise, or bequest, in addition to the personal property owned by the corporation, real estate necessary for the transaction of the corporate business, and also to purchase and accept any real estate in payment or part payment of any debt due the corporation and to sell the same; to establish by-laws and make all rules and regulations not inconsistent with the laws and constitution of the State, and of the United States of America, and not contrary to the constitution and rules and regulations of the said Memphis, North Mississippi and North Arkansas Conferences of the Methodist Episcopal Church, South, deemed expedient for the management of the corporate affairs and to appoint such subordinate officers, in addition to President and Secretary, not chosen by the governing body of said Memphis, North Mississippi and North Arkansas Conferences of the Methodist Episcopal Church, South, as the business of the corporation may require, and as we are not forbidden by the rules and regulations of said Memphis, North Mississippi and North Arkansas Conferences of the Methodist Episcopal Church, South, to designate the officers and fix the compensation of the officer.

The general welfare of society, not individual profit, is the object for which this charter is granted, and hence the members are not stockholders in the legal sense of the term, and no dividends or profits shall be divided among the members.

WE, the undersigned, apply to the State of Tennessee, by virtue of the laws of the land, for a Charter of Incorporation for the purpose and with the powers, etc., declared in the foregoing instrument.

WITNESS our hands, the 31st day of July, 1922.

(Signed) John H. Sherard
J. R. Pepper
L. M. Stratton
T. K. Riddick
L. H. Estes

STATE OF TENNESSEE
SHELBY COUNTY

Personally appeared before me, R. C. Strehl, Deputy Clerk of the County Court of said County, L. H. Estes, the within named petitioner with whom I am personally acquainted and who acknowledged that

he executed the within instrument for the purposes therein contained.
Witness my hand at office, this 31st day of July, A.D. 1922.

(Signed) R. C. Strehl, Deputy Clerk.

STATE OF TENNESSEE
SHELBY COUNTY

Personally appeared before me, R. C. Strehl, Deputy Clerk of the County Court of Shelby County aforesaid, L. H. Estes, subscribing witness to the within Charter of Incorporation, who being first sworn, deposes and says that he is acquainted with John H. Sherard, J. R. Pepper, L. K. Stratton, T. K. Riddick, the incorporators and that they acknowledged the same in his presence, to be their act and deed upon the day it bear date.
Witness my hand, at office, this 31st day of July, 1922.

(Signed) R. C. Strehl, Deputy Clerk

MHMH Corp. File
4

Secretary of State
Division of Business Services
312 Eighth Avenue North
6th Floor, William R. Snodgrass Tower
Nashville, Tennessee 37243

ISSUANCE DATE: 09/20/2004
REQUEST NUMBER: 04264516
TELEPHONE CONTACT: (615) 741-6488

CHARTER/QUALIFICATION DATE: 08/01/1922
STATUS: ACTIVE
CORPORATE EXPIRATION DATE: PERPETUAL
CONTROL NUMBER: 0054694
JURISDICTION: TENNESSEE

O:
ETHODIST HEALTHCARE
IM SHARPE
211 UNION ST
EMPHIS, TN 38104

REQUESTED BY:
METHODIST HEALTHCARE
KIM SHARPE
1211 UNION ST
MEMPHIS, TN 38104

CERTIFICATE OF EXISTENCE

, RILEY C DARNELL, SECRETARY OF STATE OF THE STATE OF TENNESSEE DO HEREBY CERTIFY THAT

"METHODIST HEALTHCARE MEMPHIS HOSPITALS"

IS A CORPORATION DULY INCORPORATED UNDER THE LAW OF THIS STATE WITH DATE OF INCORPORATION AND DURATION AS GIVEN ABOVE;
THAT ALL FEES, TAXES, AND PENALTIES OWED TO THIS STATE WHICH AFFECT THE EXISTENCE OF THE CORPORATION HAVE BEEN PAID;
THAT THE MOST RECENT CORPORATION ANNUAL REPORT REQUIRED HAS BEEN FILED WITH THIS OFFICE; AND
THAT ARTICLES OF DISSOLUTION HAVE NOT BEEN FILED; AND
THAT ARTICLES OF TERMINATION OF CORPORATE EXISTENCE HAVE NOT BEEN FILED

IR: REQUEST FOR CERTIFICATE

ON DATE: 09/20/04

	FEES	
RECEIVED:	$20.00	$0.00
TOTAL PAYMENT RECEIVED:		$20.00

RECEIPT NUMBER: 00003586278
ACCOUNT NUMBER: 00278211

IOM:
ETHODIST HEALTHCARE-CORPORATE MEMPHIS
1 UNION AVENUE
ITE 600
EMPHIS, TN 38104-0000

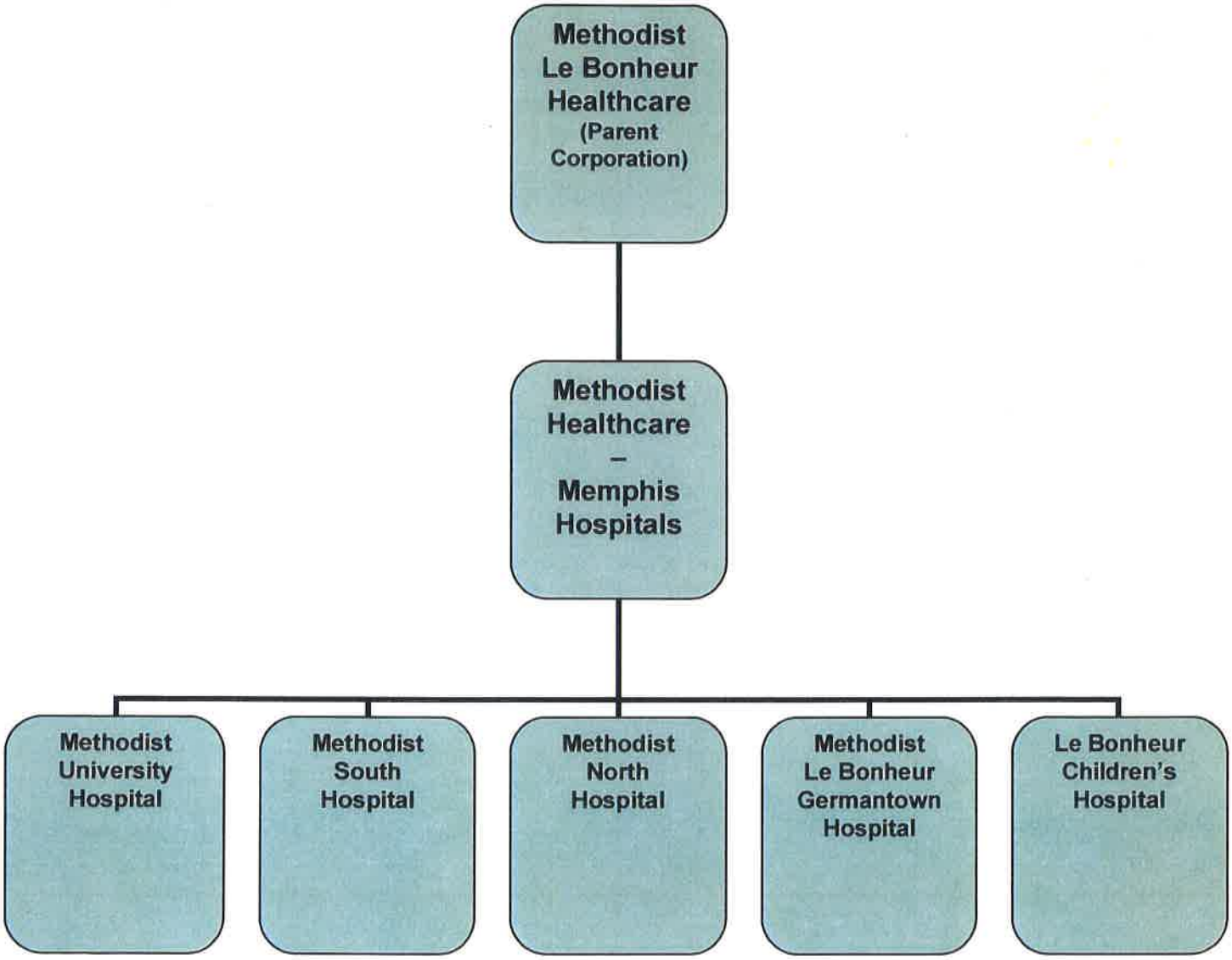
Riley C Darnell

RILEY C. DARNELL
SECRETARY OF STATE

SS-4454

A: 4 Ownership-
Legal Entity and Organization Chart

METHODIST HEALTHCARE – MEMPHIS HOSPITALS OWNERSHIP STRUCTURE ORGANIZATIONAL CHART



List of Methodist Health Care Facilities

Methodist Healthcare owns or has financial interest in the following health care facilities:

1. Methodist Healthcare – Memphis Hospitals hospital license – 100%, includes the following:

   Methodist Healthcare University Hospital – 100%

   Methodist Healthcare South Hospital – 100%

   Methodist Healthcare North Hospital – 100%

   Methodist Healthcare Le Bonheur Germantown Hospital – 100%

   Le Bonheur Children's Hospital – 100%

2. Methodist Extended Care Hospital, Inc. – 100%
3. Le Bonheur Center for Children and Parents – 100%
4. Alliance Health Services, Inc. – 100%
5. Mid-South Radiation Oncology, LLC d/b/a Methodist Germantown Radiation Oncology Center – 100%
6. North Surgery Center, L.P. – 62.5% Gen. Par
7. Methodist Surgery Center Germantown, L.P. - 55% Gen. Par.
8. Midtown Surgery Center, L.P. – 32% Lim. Par.
9. Urology Ambulatory Surgery Center, LLC – 30%
10. Le Bonheur East Surgery Center, L.P. – 35% Gen. Par.
11. Blood and Marrow Transplant Center of the Mid-South, LLC – 30%
12. HealthSouth Rehabilitation Hospital, L.P. – 30% Limited Par.
13. HealthSouth Rehabilitation Hospital North –30% Limited Par.
14. Hamilton Eye Institute Surgery Center, L.P. – 33.3%

A: 6 Site Control

This instrument prepared by and return to:
James B. McLaren, Jr.
Adams and Reese LLP
80 Monroe Avenue, Suite 700
Memphis, TN 38103-2647

MAXIMUM PRINCIPAL INDEBTEDNESS FOR TENNESSEE RECORDING TAX PURPOSES IS $0. Same indebtedness as indebtedness of the Health, Educational and Housing Facility Board of the County of Shelby, Tennessee.

NOTICE PURSUANT TO SECTION 47-28-104 OF TENNESSEE CODE ANNOTATED:

This Deed of Trust is for "commercial purposes" and secures future advances which may be "obligatory advances" as defined in § 47-28-101(a)(6) of Tennessee Code Annotated. The priority of all advances made under this Deed of Trust relates back to the time of the initial recording of this Deed of Trust and the lien of all such future advances is prior and superior to the lien of any encumbrance or conveyance arising or recorded subsequent to the recording of this Deed of Trust. This instrument covers property which is or may become so affixed to Mortgaged Property as to become fixtures and also constitutes a fixture filing, timber to be cut filing and minerals filing under § 47-9-401 and § 47-9-402 of Tennessee Code Annotated.

SECOND AMENDMENT TO TENNESSEE DEED OF TRUST WITH SECURITY AGREEMENT, AND LEASEHOLD DEED OF TRUST, ASSIGNMENT OF LEASES/RENTS, FIXTURE FILING AND FINANCIAL STATEMENT

THIS SECOND AMENDMENT TO DEED OF TRUST WITH SECURITY AGREEMENT, AND LEASEHOLD DEED OF TRUST, ASSIGNMENT OF LEASES/RENTS, FIXTURE FILING AND FINANCIAL STATEMENT, ("Second Amendment") is executed as of the 12th day of June, 2008, by **METHODIST HEALTHCARE – MEMPHIS HOSPITALS**, a Tennessee non-profit corporation, whose mailing address is 1211 Union Avenue, Suite 600, Memphis, Tennessee 38104, Party of the First Part (the "Grantor"), and **DEUTSCHE BANK NATIONAL TRUST COMPANY** (successor trustee to JPMORGAN TRUST COMPANY, NATIONAL ASSOCIATION) with offices at 6810 Crumpler Blvd., Suite 100, Olive Branch, Mississippi 38654, Attention: Dennis Gillespie, as trustee under the Master Indenture referred to herein, party of the second part (together with its successors in such trust, the "Beneficiary" or "Master Trustee").

RECITALS:

WHEREAS, the Grantor has previously executed a certain Deed of Trust dated April 17, 2002, and recorded in the Register's Office of Shelby County, Tennessee as Instrument No. 02067341 as amended by Amendment to Tennessee Deed of Trust, with Security Agreement and Leasehold Deed of Trust, Assignment of Leases/Rents, Fixture Filing and Financing Statement dated September 15, 2004 and recorded as Instrument No. 04205238 in said Register's Office (as so amended, the "Deed of Trust").

WHEREAS, the Deed of Trust secures repayment of certain obligations of Grantor issued pursuant to that certain Amended and Restated Master Trust Indenture dated as of April 1, 2002 between Grantor, Methodist – LeBonheur Healthcare and Master Trustee, as amended from time to time (as so amended, the "Master Indenture") in the current principal amount of $549,600,000.

WHEREAS, the Grantor and Master Trustee wish to include certain property owned by Grantor in fee simple or leasehold in the Mortgaged Property (as defined in the Deed of Trust).

WHEREAS, Section 6.1 of the Deed of Trust provides that Grantor may, with the consent of the Master Trustee, enter into such amendments as it may deem necessary or desirable.

WHEREAS, the Grantor and Master Trustee desire to amend the Deed of Trust as provided herein.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree that the Deed of Trust shall be amended as follows:

1. Substitution of Exhibits. The exhibit marked Exhibit A attached to the Deed of Trust (the "Former Exhibit A") shall be deleted, and Exhibit A attached hereto(the "Revised Exhibit A") shall be substituted in its place. All references to the term "Exhibit A" in the Deed of Trust shall mean and refer to the Revised Exhibit A.

2. References to Mortgaged Property. All references to the term "Mortgaged Property" as set forth in the Deed of Trust shall mean and refer to the real estate situated and being in Shelby County, Tennessee, as more particularly described in Revised Exhibit A, attached hereto.

3. Continuation of lien priority. The Deed of Trust and its lien priority shall continue in full force and effect unmodified except as otherwise provided herein.

4. Miscellaneous. Nothing in this Second Amendment is to be construed to constitute a novation of the provisions, terms and conditions of the Deed of Trust. All of the provisions, terms and conditions set forth in the Deed of Trust not specifically amended hereby are to remain in full force and effect as if this Second Amendment had not in fact been executed. To the extent a conflict arises between the terms and conditions of this Second Amendment with the terms and conditions of the Deed of Trust, the terms and conditions of this Second Amendment and of the Deed of Trust are to be construed in a light most favorable to resolving any such conflict. To the extent any such conflict can not be resolved, the terms and conditions of this Amendment are to control.

[signature pages follow]

[signature page to Second Amendment to Tennessee Deed of Trust]

IN WITNESS WHEREOF, the parties have executed (or caused to be executed) this Agreement, as of the day and year first above written.

GRANTOR:

METHODIST HEALTHCARE – MEMPHIS HOSPITALS,
a Tennessee nonprofit corporation

By: _____

Its: Executive Vice President, CFO

MASTER TRUSTEE:

DEUTSCHE BANK NATIONAL TRUST COMPANY, as Master Trustee

By: _____

Its: _____

IN WITNESS WHEREOF, the parties have executed (or caused to be executed) this Agreement, as of the day and year first above written.

GRANTOR:

METHODIST HEALTHCARE – MEMPHIS HOSPITALS,
a Tennessee nonprofit corporation

By:_____

Its:_____

MASTER TRUSTEE:

DEUTSCHE BANK NATIONAL TRUST COMPANY, as Master Trustee

By:_____

Its: Vice President

STATE OF TENNESSEE
COUNTY OF SHELBY

Before me, the undersigned, a Notary Public in and for said State and County, personally appeared Chris McLean, with whom I am personally acquainted (or proved to me on the basis of satisfactory evidence), and who, upon oath, acknowledged him/herself to be EVP, CFO (corporate office held) of Methodist Healthcare – Memphis Hospitals, the within named bargainor, a corporation, and that s/he as such EVP, CFO, executed the foregoing instrument for the purpose therein contained, by signing the name of the corporation by him/herself as EVP, CFO.

WITNESS my hand, at office, this 6 day of June, 2008.

Hilda P. Turman
Notary Public

My Commission Expires:

HILDA P. TURMAN
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF SHELBY
My Commission Expires 2011

STATE OF _____
COUNTY OF _____

Before me, the undersigned, a Notary Public in and for said State and County, personally appeared _____, with whom I am personally acquainted (or proved to me on the basis of satisfactory evidence), and who, upon oath, acknowledged him/herself to be _____ (corporate office held) of Deutsche Bank National Trust Company, the within named bargainor, a banking corporation, and that s/he as such _____, executed the foregoing instrument for the purpose therein contained, by signing the name of the corporation by him/herself as _____.

WITNESS my hand, at office, this ____ day of June, 2008.

_____
Notary Public

My Commission Expires:

_____

STATE OF TENNESSEE
COUNTY OF SHELBY

Before me, the undersigned, a Notary Public in and for said State and County, personally appeared _____, with whom I am personally acquainted (or proved to me on the basis of satisfactory evidence), and who, upon oath, acknowledged him/herself to be _____ (corporate office held) of Methodist Healthcare – Memphis Hospitals, the within named bargainor, a corporation, and that s/he as such _____, executed the foregoing instrument for the purpose therein contained, by signing the name of the corporation by him/herself as _____.

WITNESS my hand, at office, this _____ day of June, 2008.

_____
Notary Public

My Commission Expires:

_____

STATE OF MISSISSIPPI
COUNTY OF DESOTO

Before me, the undersigned, a Notary Public in and for said State and County, personally appeared Dennis D. Gillespie, with whom I am personally acquainted (or proved to me on the basis of satisfactory evidence), and who, upon oath, acknowledged him/herself to be Vice President of Deutsche Bank National Trust Company, the within named bargainor, a banking corporation, and that s/he as such Vice President, executed the foregoing instrument for the purpose therein contained, by signing the name of the corporation by him/herself as Vice President.

WITNESS my hand, at office, this 1st day of June, 2008.

_____
Notary Public

My Commission Expires:
MISSISSIPPI STATEWIDE NOTARY PUBLIC
MY COMMISSION EXPIRES APR. 6, 2011
BONDED THRU STEGALL NOTARY SERVICE

EXHIBIT A

LEGAL DESCRIPTION

PARCEL 1

Being all of the Methodist Hospitals of Memphis property as recorded in Instrument Number FE-7134 (excepting dedicated right-of-way per Plat Book 236, Page 34), and the Methodist Hospitals of Memphis property as recorded in Instrument Number DR-7376 and the Methodist Healthcare Memphis Hospitals property as recorded in Instrument Number 0402533 at the Shelby County Register's Office, City of Memphis, State of Tennessee, being more particularly described by metes and bounds as follows:

Commencing at the centerline intersection of Poplar Avenue (106' right of way) with Germantown Boulevard (80' right of way); thence along the centerline of said Poplar Avenue, South 60 degrees 15 minutes 00 seconds East a distance of 529.69' to a point; thence departing from and perpendicular to said centerline, South 29 degrees 45 minutes 00 seconds West a distance of 53.00' to a point (found iron pin) on the southwest right of way line of Poplar Avenue, said point being the intersection of said southwest right of way line of Poplar Avenue with the east line of the Tempus II Partnership property as recorded in Instrument Number LE-1393 as recorded in the Shelby County Register's Office, City of Memphis, State of Tennessee, said point being the ***TRUE POINT OF BEGINNING***; thence along said southwest right of way line, South 60 degrees 15 minutes 00 seconds East a distance of 635.64' to a point (found iron pin 2.25' southwest) being the intersection of said southwest right of way line with the west line of the Nationwide Health Properties, Inc. property as recorded in Instrument Number GP-8241 in said Register's Office; thence departing from said southwest right of way line along the west line of said Nationwide Health Properties, Inc. property, South 28 degrees 54 minutes 10 seconds West a distance of 387.55' to a point being the southwest corner of said Nationwide Health Properties, Inc. property, said point being on the north line of the Homes Trust property as recorded in Instrument Number KW-6984 at said Register's Office; thence along said north line, South 88 degrees 42 minutes 25 seconds West a distance of 28.76' to a point (found iron pipe) at the northwest corner of said Holmes Trust property; thence along the west line of said Holmes Trust property, South 00 degrees 44 minutes 16 seconds East a distance of 233.62' to a point (found iron pipe) at the northeast corner of the Dabney S. Wellford & wife, Carolyn M. Wellford property as recorded in Instrument Number HS-1520 at said Register's Office; thence North 87 degrees 21 minutes 49 seconds West a distance of 158.04' to a point (set iron pin) being the northwest corner of said Dabney S. Wellford & wife, Carolyn M. Wellford property; thence along the west line of said Dabney S. Wellford & wife, Carolyn M. Wellford property, South 01 degrees 06 minutes 30 seconds West a distance of 795.45' to a point being the intersection of said west line of the Dabney S. Wellford & wife, Carolyn M. Wellford property with the north right of way line of Dogwood Road (45' right of way, 25' from centerline) as dedicated per Plat Book 236, Page 34 at said Register's Office; thence departing from said west line along said north right of way line of Dogwood Road per Plat Book 236, Page 34, North 89 degrees 18 minutes 20 seconds West a distance of 223.31' to a point of curvature; thence continuing along said north right of way line in a northwesterly direction along the arc of a curve to the right having a radius of 1000.00' (Long Chord = North 83 degrees 35 minutes 49 seconds West, 198.84') an arc distance of 199.17' to a point; thence continuing along said north right of way line, North 77 degrees 53 minutes 17 seconds West a distance of 156.54' to a point of curvature; thence continuing along said north right of way line in a northwesterly direction along the arc of a curve to the left having a radius of 685.00' (Long Chord = North 82 degrees 47 minutes 19 seconds West, 117.04') an arc distance of 117.18' to a point; thence continuing along said north right of way line, North 87 degrees 41 minutes 22 seconds West a distance of 127.42' to a point (found

iron pin 5.00' south) being the intersection of said north right of way line (25' from centerline) with the most southerly east line of the Genetta Barry Roast, Trustee property as recorded per Instrument Number 06197186 at said Register's Office; thence along a portion of said most southerly east line, North 00 degrees 09 minutes 41 seconds West a distance of 45.67' to a found angle iron being an internal corner of said Genetta Barry Roast, Trustee property; thence along the southernmost north line of said Genetta Barry Roast, Trustee property, South 89 degrees 46 minutes 45 seconds West, a distance of 98.07 feet (call 98.19 feet) to a found 1/2 inch rebar, said rebar being an internal corner of said Genetta Barry Roast, Trustee property; thence along the east line of said Genetta Barry Roast, Trustee property and the east line of the Charles E. Frankum & Linda L. Frankum property as recorded per Instrument Number 04118050 at said Register's Office, North 00 degrees 38 minutes 30 seconds East, a distance of 250.88 feet, (call 255.12 feet), to a found 1 inch iron pipe, said iron pipe being the northeast corner of said Frankum property; thence along the north line of said Frankum property, South 80 degrees 56 minutes 26 seconds West, a distance of 238.51 feet, (call 239.61 feet), to a point in the east line of Germantown Road (Right of Way Varies), said point being the northwest corner of said Frankum property, said point being witnessed by a 1 inch square metal peg (0.93' West, 0.15' South), said peg being on the prolongation of the north line of said Frankum property and being 309.96 feet north of the centerline of Dogwood Road (40 foot Right of Way) as measured perpendicular to said centerline; thence departing from said northwest corner along said east line of Germantown Road the following seven (7) courses;

1. North 03 degrees 59 minutes 01 seconds West, a distance of 11.57 feet (call 15.80 feet) to a point of curvature;
2. thence in a Northeasterly direction along the arc of a tangent curve to the right having a radius of 654.50 feet (long chord bearing = North 07 degrees 32 minutes 30 seconds East, long chord distance = 261.53 feet) an arc distance of 263.31 feet to a point of compound curvature;
3. thence in a Northeasterly direction along the arc of a non-tangent curve to the right having a radius of 343.00 feet (long chord bearing = North 31 degrees 37 minutes 41 seconds East, long chord distance = 37.20 feet) an arc distance of 37.21 feet to a point of tangency;
4. thence North 34 degrees 44 minutes 10 seconds East, a distance of 342.04 feet to a point of curvature;
5. thence in a Northeasterly direction along the arc of a tangent curve to the left having a radius of 891.41 feet (long chord bearing = North 31 degrees 12 minutes 43 seconds East, long chord distance = 109.59 feet) an arc distance of 109.66 feet, (call 105.76 feet), to a set chisel mark, said chisel mark being the westernmost southwest corner of the Methodist Hospitals of Memphis property (DR-7376)
6. thence in a non-tangent direction along the arc of a curve to the left having a radius of 858.52' (Long Chord = North 20 degrees 44 minutes 02 seconds East, 228.03') an arc distance of 228.71' to a point of tangency;
7. thence continuing along said east right of way line, North 13 degrees 06 minutes 08 seconds East, 108.59' to a point (found iron pin) being the intersection of said east right of way line with the south line of the Spectrum Properties property as recorded in Instrument Number FN-6147 at said Register's Office;

thence departing from said east right of way line along said south line, South 80 degrees 47 minutes 47 seconds East a distance of 103.66' to a point (found iron pin) being the southeast corner of said Spectrum Properties property; thence along the east line of said Spectrum Properties property, North 00 degrees 40 minutes 34 seconds West a distance of 100.05' to a

point (found iron pin) being the northeast corner of said Spectrum Properties property; thence along the north line of said Spectrum Properties property, North 79 degrees 57 minutes 41 seconds West a distance of 79.71' to a point (found chisled 'x') being the intersection of said north line with said east right of way line of Germantown Boulevard; thence along said east right of way line, North 13 degrees 06 minutes 08 seconds East a distance of 236.23' to a point (found iron pin) being the intersection of said east right of way line with the south line of Lot 2 of the Poplar-Germantown subdivision as recorded in Plat Book 63, page 64 at said Register's Office; thence departing from said east right of way line along said south line, South 75 degrees 38 minutes 36 seconds East a distance of 132.41' to a point being the southeast corner of said Lot 2 of the Poplar-Germantown subdivision; thence along the east line of said Lot 2, North 30 degrees 03 minutes 24 seconds East a distance of 40.51' to a point (found iron pin) being the western most southwest corner of said Tempus II Partnership property as recorded in Instrument Number LE-1393 at said Register's Office; thence along the most southeast lines of said Tempus II Partnership property the following five (5) calls:

1. South 60 degrees 09 minutes 44 seconds East a distance of 118.48' to a point (found iron pin) being an interior corner of said Tempus II Partnership property;
2. thence North 30 degrees 08 minutes 48 seconds East a distance of 12.73' to a point (found iron pin) being an interior corner of said Tempus II Partnership property;
3. thence South 59 degrees 51 minutes 12 seconds East a distance of 18.82' to a point (found iron pin) being an interior corner of said Tempus II Partnership property;
4. thence North 30 degrees 08 minutes 48 seconds East a distance of 60.01' to a point being an interior corner of said Tempus II Partnership property;
5. thence along a line being parallel with said centerline of Poplar Avenue, South 60 degrees 15 minutes 00 seconds East a distance of 157.88' to a point being the most easterly southeast corner of said Tempus II Partnership property;

thence along the east line of said Tempus II Partnership property, North 29 degrees 16 minutes 57 seconds East a distance of 113.02' to said ***TRUE POINT OF BEGINNING.***

Said described properties containing 1,608,712 square feet or 36.931 Acres, more or less.

LEGAL DESCRIPTION TAKEN FROM SURVEY PREPARED BY ALLEN & HOSHALL, 1661 INTERNATIONAL DRIVE, MEMPHIS, TENNESSEE 38120 DATED JUNE 9, 2008.

AND

PARCEL II

Being all of the **Methodist Hospital** properties as described in and recorded in Deed Books 928-368, 947-592, 1811-200 and 1638-590 in the Shelby County Register's Office, City of Memphis, State of Tennessee and being more particularly described by metes and bounds as follows:

Commencing at the centerline intersection of Union Avenue (right of way varies) with Claybrook Street (50' right of way); thence along the centerline of said Claybrook Street, South 01 degrees 23 minutes 43 seconds West a distance of 38.07' to a point; thence departing from and perpendicular to said centerline, North 88 degrees 36 minutes 17 seconds West a distance of 25.00' to a point being the intersection of the south right of way line of said Union Avenue with the west right of way line of said Claybrook Street, said point being the ***TRUE POINT OF BEGINNING;*** thence along said west right of way line of Claybrook Street, South 01 degrees 23 minutes 43 seconds West a distance of 408.58' (411.07' called) to a point being the intersection

of said west right of way line of Claybrook Street with the north right of way line of Eastmoreland Road (50' right of way); thence along said north right of way line of Eastmoreland Road, North 88 degrees 28 minutes 13 seconds West a distance of 509.92' (510.32' called) to a point of curvature; thence continuing along said north right of way line in a northwesterly direction along the arc of a curve to the right having a radius of 230.36' (Long Chord = North 72 degrees 16 minutes 43 seconds West, 128.47') an arc distance of 130.20' (measured and called) to a point of reverse curvature; thence continuing along said north right of way line in a northwesterly direction along the arc of a curve to the left having a radius of 283.20' (Long Chord = North 70 degrees 22 minutes 52 seconds West, 139.85') an arc distance of 141.31' (measured and called) to a point being the intersection of said north right of way line of Eastmoreland Road with the east right of way line of Bellevue Boulevard (70' right of way); thence along said east right of way line of Bellevue Boulevard, North 00 degrees 02 minutes 42 seconds West a distance of 326.12' (measured and called) to a point of curvature; thence continuing along said east right of way line in a northeasterly direction along the arc of a curve to the right having a radius of 114.00' (Long Chord = North 09 degrees 58 minutes 50 seconds East, 39.69') an arc distance of 39.90' (40.24 called) to a point of compound curvature; thence continuing along said east right of way line in a northeasterly direction along the arc of a curve to the right having a radius of 34.00' (Long Chord = North 58 degrees 04 minutes 08 seconds East, 41.92') an arc distance of 45.17' (45.16' called) to a point on said south right of way line of Union Avenue being 40.00' from centerline; thence along said south right of way line of Union Avenue, South 83 degrees 52 minutes 05 seconds East a distance of 735.80' (736.98' called) to said ***TRUE POINT OF BEGINNING***.

Said described properties containing 328,129 square feet or 7.533 Acres, more or less.

LEGAL DESCRIPTION TAKEN FROM SURVEY PREPARED BY ALLEN & HOSHALL, 1661 INTERNATIONAL DRIVE, MEMPHIS, TENNESSEE 38120 DATED JUNE 9 , 2008.

AND

PARCEL III

Tract 1:

THE PROPERTY LEASED TO LEBONHEUR CHILDREN'S HOSPITAL, INC. AS RECORDED IN INSTRUMENTS M1-0767, AMENDED IN W3-8063, M1-0768, AMENDED IN W3-7805, AND W4-3422, ALL OF RECORD IN THE SHELBY COUNTY REGISTER'S OFFICE, LOCATED IN MEMPHIS, SHELBY COUNTY, TENNESSEE AND BEING MORE PARTICULARLY DESCRIBED AS FOLLOWS:

BEGINNING AT THE INTERSECTION OF THE NORTH LINE OF ADAMS AVENUE (50.00 FOOT RIGHT-OF-WAY) WITH THE EAST LINE OF DUNLAP STREET (80.00 FOOT RIGHT-OF-WAY); THENCE N9°21'35"E ALONG THE EAST LINE OF SAID DUNLAP STREET A DISTANCE OF 315.06 FEET TO A POINT ON THE SOUTH LINE OF WASHINGTON AVENUE; THENCE S80°42'11"E ALONG THE SOUTH LINE OF SAID WASHINGTON AVENUE A DISTANCE OF 696.89 FEET TO A POINT ON THE WEST LINE OF THE CITY OF MEMPHIS PROPERTY; THENCE ALONG THE WEST LINE OF THE SAID CITY OF MEMPHIS PROPERTY THE FOLLOWING CALLS AND DISTANCES:

S9°21'35"W - 154.14 FEET;
N80°42'11"W - 24.00 FEET;

S54°19'42"W - 14.15 FEET;
S9°21'35"W - 35.00 FEET;
S80°42'11"E - 34.00 FEET;
S9°21'35"W - 172.83 FEET

TO A POINT ON THE NORTH LINE OF SAID ADAMS AVENUE; THENCE N63°20'42"W ALONG THE NORTH LINE OF SAID ADAMS AVENUE A DISTANCE OF 102.80 FEET TO THE POINT OF CURVATURE; THENCE CONTINUING ALONG THE NORTH LINE OF SAID ADAMS AVENUE FOLLOWING A 661.70 FOOT RADIUS CURVE TO THE LEFT AN ARC DISTANCE OF 206.93 FEET (CHORD N72°18'15"W 206.09 FEET) TO THE POINT OF TANGENCY; THENCE N81°15'48"W AND CONTINUING ALONG THE NORTH LINE OF SAID ADAMS AVENUE A DISTANCE OF 394.85 FEET TO THE POINT OF BEGINNING AND CONTAINING 222,573 SQUARE FEET, OR 5.110 ACRES.

LEGAL DESCRIPTION TAKEN FROM SURVEY PREPARED BY THE REAVES FIRM, 5118 PARK AVENUE, SUITE 400, MEMPHIS, TENNESSEE 38117 DATED JUNE 4, 2008.

LESS AND EXCEPT:

BEING A DESCRIPTION OF THE PROPERTY LEASED TO LEBONHEUR CHILDREN'S HOSPITAL, INC. AS RECORDED IN INSTRUMENT W4-3422 AT THE SHELBY COUNTY REGISTER'S OFFICE, LOCATED IN MEMPHIS, SHELBY COUNTY, TENNESSEE AND BEING MORE PARTICULARLY DESCRIBED AS FOLLOWS:

COMMENCING AT THE INTERSECTION OF THE NORTH LINE OF ADAMS AVENUE (50.00 FOOT RIGHT-OF-WAY) WITH THE EAST LINE OF DUNLAP STREET (80.00 FOOT RIGHT-OF-WAY); THENCE S81°15'48"E ALONG THE NORTH LINE OF SAID ADAMS AVENUE A DISTANCE OF 394.85 FEET TO THE POINT OF CURVATURE; THENCE CONTINUING ALONG THE NORTH LINE OF SAID ADAMS AVENUE FOLLOWING A 661.70 FOOT RADIUS CURVE TO THE RIGHT AN ARC DISTANCE OF 206.93 FEET (CHORD S72°18'15"E 206.09 FEET) TO THE POINT OF TANGENCY; THENCE S63°20'42"E AND CONTINUING ALONG THE NORTH LINE OF SAID ADAMS AVENUE A DISTANCE OF 24.02 FEET TO THE POINT OF BEGINNING; THENCE N9°21'35"E ALONG THE EASTERN MOST EAST LINE OF PARCEL 7-1 OF THE PROPERTY SHOWN ON THE SUBDIVISION OF BLOCK 2, 7, & 8 OF THE MEMPHIS MEDICAL CENTER AREA AS RECORDED IN PLAT BOOK 31, PAGE 18 AT SAID REGISTER'S OFFICE, A DISTANCE OF 194.33 FEET TO A POINT ON THE SOUTH LINE OF PARCEL 7-4 OF SAID SUBDIVISION; THENCE S80°42'11"E ALONG THE SOUTH LINE OF SAID PARCEL 7-4 A DISTANCE OF 51.22 FEET TO A POINT ON THE WEST LINE OF THE CITY OF MEMPHIS PROPERTY; THENCE ALONG THE WEST LINE OF THE SAID CITY OF MEMPHIS PROPERTY THE FOLLOWING CALLS AND DISTANCES:

S54°19'42"W - 14.15 FEET;
S9°21'35"W - 35.00 FEET;
S80°42'11"E - 34.00 FEET;
S9°21'35"W - 172.83 FEET

TO A POINT ON THE NORTH LINE OF SAID ADAMS AVENUE; THENCE N63°20'42"W ALONG THE NORTH LINE OF SAID ADAMS AVENUE A DISTANCE OF 78.78 FEET TO

THE POINT OF BEGINNING.

LEGAL DESCRIPTION TAKEN FROM SURVEY PREPARED BY THE REAVES FIRM, 5118 PARK AVENUE, SUITE 400, MEMPHIS, TENNESSEE 38117 DATED JUNE 4, 2008.

Tract 2:

BEING A SURVEY OF THE METHODIST HEALTHCARE - MEMPHIS HOSPITALS PROPERTY AS RECORDED IN INSTRUMENT 07165301 AT THE SHELBY COUNTY REGISTER'S OFFICE, LOCATED IN MEMPHIS, SHELBY COUNTY, TENNESSEE AND BEING MORE PARTICULARLY DESCRIBED AS FOLLOWS:

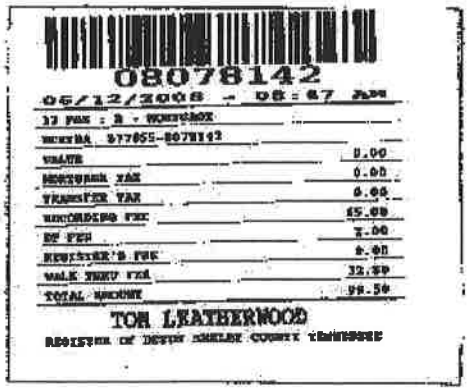
BEGINNING AT THE INTERSECTION OF THE EAST LINE OF DUNLAP STREET (80.00 FOOT PUBLIC RIGHT-OF-WAY) WITH THE NORTH LINE OF WASHINGTON AVENUE (80.00 FOOT PUBLIC RIGHT-OF-WAY); THENCE N9°22'55"E ALONG THE EAST LINE OF SAID DUNLAP STREET A DISTANCE OF 269.58 FEET TO A POINT OF CURVATURE, SAID POINT OF CURVATURE BEING THE SOUTHWEST CORNER OF THE CITY OF MEMPHIS RIGHT-OF-WAY AS RECORDED IN INSTRUMENT E1-8163 AT SAID REGISTER'S OFFICE; THENCE ALONG A 20.00 FOOT RADIUS CURVE TO THE RIGHT AN ARC DISTANCE OF 30.74 FEET (CHORD N53°25'09"E 27.80 FEET) TO THE POINT OF TANGENCY; THENCE S82°32'38"E ALONG THE SOUTH RIGHT-OF-WAY LINE OF POPLAR AVENUE AS DESCRIBED IN INSTRUMENT E1-8163 A DISTANCE OF 249.87 FEET TO A POINT ON THE ORIGINAL SOUTH RIGHT-OF-WAY LINE OF POPLAR AVENUE, SAID POINT BEING 40.00 FEET SOUTH OF THE PHYSICAL CENTERLINE OF SAID POPLAR AVENUE (80.00 FOOT PUBLIC RIGHT-OF-WAY); THENCE S80°58'10"E ALONG THE ORIGINAL SOUTH RIGHT-OF-WAY LINE OF POPLAR AVENUE A DISTANCE OF 437.26 FEET TO A POINT OF CURVATURE; THENCE ALONG A 30.00 FOOT RADIUS CURVE TO THE RIGHT AN ARC DISTANCE OF 45.13 FEET (CHORD S37°52'29"E 40.99 FEET) TO A POINT OF REVERSE CURVATURE, SAID POINT LIES ON THE WEST RIGHT-OF-WAY LINE OF PAULINE STREET (80.00 FOOT PUBLIC RIGHT-OF-WAY); THENCE ALONG THE WEST LINE OF SAID PAULINE STREET ALONG A 376.18 FOOT RADIUS CURVE TO THE LEFT AN ARC DISTANCE OF 166.50 FEET (CHORD S7°27'37"E 165.15 FEET) TO A POINT OF REVERSE CURVATURE; THENCE ALONG A 50.00 FOOT RADIUS CURVE TO THE RIGHT AN ARC DISTANCE OF 70.04 FEET (CHORD S19°59'25"W 64.45 FEET) TO THE POINT OF TANGENCY, SAID POINT LIES ON THE NORTH RIGHT-OF-WAY LINE OF SAID WASHINGTON AVENUE; THENCE S60°07'15"W ALONG THE NORTH LINE OF SAID WASHINGTON AVENUE A DISTANCE OF 43.99 FEET TO A POINT OF CURVATURE; THENCE CONTINUING ALONG THE NORTH LINE OF SAID WASHINGTON AVENUE ALONG A 100.00 FOOT RADIUS CURVE TO THE RIGHT AN ARC DISTANCE OF 68.38 FEET (CHORD S79°42'32"W 67.05 FEET) TO THE POINT OF TANGENCY; THENCE N80°42'11"W ALONG THE NORTH LINE OF SAID WASHINGTON AVENUE A DISTANCE OF 675.20 FEET TO THE POINT OF BEGINNING AND CONTAINING 224,273 SQUARE FEET, OR 5.149 ACRES.

LEGAL DESCRIPTION TAKEN FROM SURVEY PREPARED BY THE REAVES FIRM, 5118 PARK AVENUE, SUITE 400, MEMPHIS, TENNESSEE 38117 DATED JUNE 5, 2008.

Tom Leatherwood

Shelby County Register

As evidenced by the instrument number shown below, this document has been recorded as a permanent record in the archives of the Office of the Shelby County Register.



1075 Mullins Station, Suite W165 – Memphis, Tennessee 38134 – (901) 379-7500
Website: http://register.shelby.tn.us – Email: Tom.Leatherwood@shelbycountytn.gov

B:II(E) (3)
Vendor Quotes

PHILIPS HEALTHCARE
A division of Philips Electronics North America Corporation
22100 Bothell Everett Highway
P.O. Box 3003
Bothell, Washington 98041-3003

PHILIPS

Quotation #: 1-1EN38XN	**Rev:** 1	**Effective From:** 10-Feb-16	**To:** 10-Apr-16

Presented To:

METHODIST HEALTHCARE UNIVERSITY HOSPITAL
1265 UNION AVE
MEMPHIS, TN 38104-3499

Tel:

Alternate Address:

Presented By:

Brad Behanna
Account Manager
Tel: (615) 585-6739
Fax:

Kevin Fultz
Regional Manager
Tel:
Fax:

Date Printed: 10-Feb-16

Submit Orders To:
22100 BOTHELL EVERETT HWY
BOTHELL WA 98021
Tel: (888) 564-8643
Fax: (425) 458-0390

The Service information contained in this Quote is subject to a separate service proposal.

IMPORTANT NOTICE: Health care providers are reminded that if the transactions herein include or involve a loan or discount (including a rebate or other price reduction), they must fully and accurately report such loan or discount on cost reports or other applicable reports or claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, such as may be required by state or federal law, including but not limited to 42 CFR 1001.952(h).

Quote Solution Summary

Line #	Product	Qty	Price
	100247 Allura Xper FD20 OR Table	1	$1,972,443.00
		Equipment Total:	$1,972,443.00

Solution Summary Detail

Product	Qty	Each	Monthly	Price
100247 Allura Xper FD20 OR Table	1	$1,972,443.00		$1,972,443.00
SVC0130 Protection POS			$7,818.75	

The Service information contained in this Quote is subject to a separate service proposal.

Buying Group: **HEALTHTRUST PURCHASING GROUP** **Contract #:** **500005**

Addt'l Terms:

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

Payment **0% Down, 80% Upon Delivery, 20% Due When the Product is Available for First Patient Use, Net due 30 days from date of invoice**

NET PRICE $1,972,443.00

Buying Group: HEALTHTRUST PURCHASING GROUP Contract #: 500005

Addt'l Terms:

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

Price above does not include any applicable sales taxes.

The preliminary delivery request date for this equipment is:_____.

If you do not issue formal purchase orders indicate by initialing here_____.

Tax Status:

Taxable_____ Tax Exempt_____

If Exempt, please indicate the Exemption Certification Number:_____, and attach a copy of the certificate.

Delivery/Installation Address:

_____

_____

_____

Invoice Address:

_____

_____

_____

Contact Phone #:

_____

Contact Phone #:

_____

Purchaser approval as quoted:

_____

Date:

_____

Title:

_____

This quotation is signed and accepted by an authorized representative in acknowledgement of the system configuration, terms and conditions stated herein.

PHILIPS HEALTHCARE
A division of Philips Electronics North America Corporation
22100 Bothell Everett Highway
P.O. Box 3003
Bothell, Washington 98041-3003

PHILIPS

Quotation #: 1-1EN38XN	**Rev.** 1	**Effective From:** 02/10/2016	**To:** 04/10/2016

Presented To:

METHODIST HEALTHCARE UNIVERSITY HOSPITAL
1265 UNION AVE
MEMPHIS, TN 38104-3499

Tel:

Alternate Address:

Presented By:

Brad Behanna
Account Manager
Tel: (615) 585-6739
Fax:

Kevin Fultz
Regional Manager
Tel:
Fax:

Date Printed: 10-Feb-16

Submit Orders To: 22100 Bothell Everett Hwy
Bothell, WA 98021-8431
Tel: (800) 982-2011
Fax: (425) 487-8110

IMPORTANT NOTICE: Health care providers are reminded that if the transactions herein include or involve a loan or discount (including a rebate or other price reduction), they must fully and accurately report such loan or discount on cost reports or other applicable reports or claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, such as may be required by state or federal law, including but not limited to 42 CFR 1001.952(h).

Model	Months	Qty	Service Plan
100247 Allura Xper FD20 OR Table	48	1	SVC0130 Philips RightFit Service Agreement Protection POS

Home Office Use Only		
Site #	**Start Date**	**End Date**

POINT OF SALE SERVICE CONTRACT SECTION

Philips Ultrasound Customer Services Ranked #1 by Customers in IMV ServiceTrakTM All Systems Survey in 2013 for the 21st consecutive year

Allura Xper FD20 OR Table	
Additional Equipment Covered	**Part #**
Mark 7 Arterion, Table Mount	**989801220158**
-Comprehensive parts and labor support for CV INJECTOR.	
FlexV XL xperHD for 3rd p. MCS	**NCVB775**
-Repair of the Philips FlexVision viewing solution	
FD20_Ceiling ORT FlexMove	**NNAE968**
Interventional Tools Hardware	**NCVB878**
-Comprehensive parts and labor support for Interventional Hardware and Software	
25 kVA Fluoro only UPS - UPC	**989801220281**
- All labor and parts (except batteries) as necessary. - Includes One UPS Module PM and One Battery PM per year during Normal Business Hours (Mon-Fri 8am-5pm) on three phase UPS units	

Item #	Part #	Description
1	SVC0130	**Philips RightFit Service Agreement Protection POS**

Thank you for the opportunity to provide this proposed Philips RightFit Service Agreement. Our Protection Service Agreement offers you robust security, a hands-on relationship with Philips, and open communications.

SERVICE DELIVERY:

- 98% uptime guarantee for each contract year. This provides assurance of the equipment availability to scan patients, as described in the uptime guarantee exhibit.

LABOR:

- Labor and travel coverage for on-site service 8:00 am - 9:00 pm, Monday - Friday, excluding Philips published holidays. The warranty period is included.
- Preferential Scheduling of service calls for service contract customers.
- On-site Response. At customer's request, Philips service goal is to be on-site within 4 hours.
- Planned maintenance coverage from 8:00 am – 9:00 pm, Monday – Friday, excluding Philips published holidays. Coverage includes activities performed according to a schedule to review safety, image quality, calibrations, equipment cleaning, performance trials and any other planned service prescribed by Philips. Philips current recommendation for IXR systems is 1 - 2 times per year depending on the specific product model.
- Preferred rates for labor and travel. This includes reduced hourly rates for labor and travel for corrective or planned maintenance outside of Service Agreement coverage hours.

PARTS:

- Standard parts coverage. This provides coverage on parts used to maintain and repair the equipment including both hardware and software items.
- Earliest next day a.m. parts delivery. This provides delivery in most areas that can be accommodated by 8:30 am to fit the urgency of your need. (Actual time depends on local shipper delivery schedule and delivery restrictions for oversized or hazardous parts).

STRATEGIC PARTS COVERAGE:

- X-ray tube(s), Flat Detector(s), and Image Intensifier(s).

LIFECYCLE:

- Operating system software and hardware reliability updates. This includes on-site or remote labor, travel and parts necessary to complete safety, performance and reliability modifications to existing equipment software or hardware.
- 20% discount on any items selected from Philips Life Solutions catalog, excluding power monitoring.

CUSTOMER CARE SOLUTIONS CENTER:

- 24/7 Technical telephone support.
- Clinical telephone support from 8:00 am - 9:00 pm, Monday – Friday.
- Remote Services. This supports remote system diagnostics and monitoring. Philips equipment is connected via an Internet secure single point of access network to our solutions center as described in the Terms and Conditions exhibit. Features may vary by equipment and software release level.

SOLUTION ENHANCEMENTS:

- Philips Service Information. This contains important service management reports through a secure Internet site. Information on equipment service status, historical service performance, engineer response time, and planned maintenance schedules is available.
- Annual customer loyalty meetings. This includes a review of current and future performance goals of Philips equipment and service.

Allura Xper FD20 OR Table

Service Plan: SVC0130 Philips RightFit Service Agreement Protection POS
Quantity: 1

To commence at a time of system warranty expiration with the exception of In-Warranty Coverage and selected Supplement Items Plans

Select Payment Terms Desired:

Select Choice *	Payments Plans	Single System Net	Total Net
☐	48 Monthly Payments at	$7,819	$7,819
☐	16 Quarterly Payments at	$23,456	$23,456
☐	4 Yearly Payments at	$93,825	$93,825
☐	Single Payment at	$375,300	$375,300

*** If no selection is made, the default choice will be monthly payments.**

Prices above do not include any applicable sales taxes

The service agreement payment does not include optional equipment. If optional equipment is purchased please see attached Equipment Configuration Option Pricing (if available) or contact your Account Manager for amended service pricing.

Buying Group: HEALTHTRUST PURCHASING GROUP **Contract #:** 500005

Addt'l Terms:

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

For services performed outside the contract hours of coverage, Philips will request a Purchase Order before dispatching a Field Service Engineer.

Our facility does not issue formal purchase orders. We authorize payments 'in lieu of a Purchase Order' for the equipment as described in Philips Healthcare Service Agreement. Initialed: _____

Our facility does issue formal purchase orders, however, due to our business/system limitations, we cannot issue a formal purchase order until _____ days prior to warranty expiration. Initialed: _____

Customer Agreement as Quoted

Upon customer signing and acceptance by an authorized Philips representative, this document constitutes a contract and customer agrees to be bound by all terms hereof which include IMPORTANT LIMITATIONS OF LIABILITY.

BY: X _____
Customer Signature

_____
Printed Name

Title _____ Date _____

For Headquarters Use Only

Philips by its acceptance thereof, agrees to provide maintenance service for the equipment listed above in accordance with all terms.

_____
Signature

Title _____ Date _____

GE Healthcare

Date: 02-02-2016
Quote #: PR3-C62407
Version #: 1

Methodist UT Hospital
1265 Union Ave
Memphis TN 38104-3415

Attn: Mary Carol
1265 Union Ave Suite 700 Memphis
TN 38104-

Customer Number : 87491
Quotation Expiration Date: 04-28-2016

The terms of the Master Purchasing Agreement, Strategic Alliance Agreement or GPO Agreement referenced below as the Governing Agreement shall govern this Quotation. No additional or different terms shall apply unless agreed to in writing by authorized representatives of both parties.

Governing Agreement:	HPG
Terms of Delivery:	FOB Destination
Billing Terms:	80% delivery / 20% Installation
Payment Terms:	NET 30
Total Quote Net Selling Price:	$3,959,766.67

INDICATE FORM OF PAYMENT:

If "GE HFS Loan" or "GE HFS Lease" is NOT selected at the time of signature, then you may NOT elect to seek financing with GE Healthcare Financial Services (GE HFS) to fund this arrangement after shipment.

____Cash/Third Party Loan

____GE HFS Lease

____GE HFS Loan

____Third Party Lease (please identify financing company)

By signing below, each party certifies that it has not made any handwritten modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

Each party has caused this agreement to be executed by its duly authorized representative as of the date set forth below.

CUSTOMER

_____ _____
Authorized Customer Signature Date

_____ _____
Print Name Print Title

_____
Purchase Order Number (if applicable)

GE HEALTHCARE

J Mcnatt 02-02-2016
Signature Date

Product Sales Specialist

Email: J.Mcnatt@med.ge.com
Mobile: +1 865 382 7555
Fax: 865-381-1558

GE Healthcare

Date: 02-02-2016
Quote #: PR3-C62407
Version #: 1

Total Quote Selling Price	**$3,959,766.67**
Trade-In and Other Credits	$0.00
Total Quote Net Selling Price	**$3,959,766.67**

To Accept this Quotation

Please sign and return this Quotation together with your Purchase Order To:
J Mcnatt
Mobile: +1 865 382 7555
Email: J.Mcnatt@med.ge.com
Fax: 865-381-1558

Payment Instructions

Please **Remit** Payment for invoices associated with this quotation to:
GE Healthcare
P.O. Box 96483
Chicago, IL 60693

To Accept This Quotation

- Please sign the quote and any included attachments (where requested).
- If requested, please indicate, your form of payment.
- If you include the purchase order, please make sure it references the following information
  - The correct Quote number and version number above
  - The correct Remit To information as indicated in **"Payment Instructions"** above
  - The correct SHIP TO site name and address
  - The correct BILL TO site name and address
  - The correct Total Quote Net Selling Price as indicated above

"Upon submission of a purchase order in response to this quotation, GE Healthcare requests the following to evidence agreement to contract terms.
Signature page on quote filled out with signature and P.O. number.
**********OR**********
Verbiage on the purchase order must state one of the following: (i) Per the terms of Quotation #_____; (ii) Per the terms of GPO#_____; (iii) Per the terms of MPA #_____; or (iv) Per the terms of SAA #_____. Include the applicable quote/agreement number with the reference on the purchase order.
In addition, source of funds (choice of: Cash/Third Party Loan or GE HFS Lease or GE HFS Loan or Third Party Lease through _____), must be indicated, which may be done on the quote signature page (for signed quotes), on the purchase order (where quotes are not signed) or via a separate written source of funds statement (if provided by GE Healthcare)."

GE Healthcare

Date: 02-02-2016
Quote #: PR3-C62407
Version #: 1

02-02-2016

GPO Agreement Reference Information

Customer:	Mary Carol
Contract Number:	500043, 500352, 500174, 500072, 500151, 500150, 500277, 1451, 1450, 000903
Start Date:	
End Date:	05/31/2017
Billing Terms:	80% delivery / 20% Installation
Payment Terms:	NET 30
Shipping Terms:	FOB Destination

NOTICE REGARDING MAGNETIC RESONANCE ("MR") PRODUCTS. This notice applies only to the following GE Healthcare products: MR: Discovery MR750, Discovery MR750w, Discovery MR450 and Optima MR450w. GE Healthcare has reclassified several advanced software tools and associated documentation to a GE Healthcare Technical Service Technology package that GE Healthcare feels will bring greater value and interest to our customers. GE Healthcare will continue to provide trained Customer employees with access to the GE Healthcare Technical Service Technology package under a separate agreement. GE Healthcare will continue to provide customers and their third party service providers with access to software tools and associated documentation in order to perform basic service on the CT, MR and NM products listed above upon a request for registration for such access. This will allow GE Healthcare to react faster to the future service needs of GE Healthcare customers. If you have any questions, you can contact your sales Service Specialist.

Offer subject to the Terms and Conditions of the applicable Group Purchasing Agreements currently in effect between GE Healthcare and HealthTrust Purchasing Group includes 500043 (Imaging).

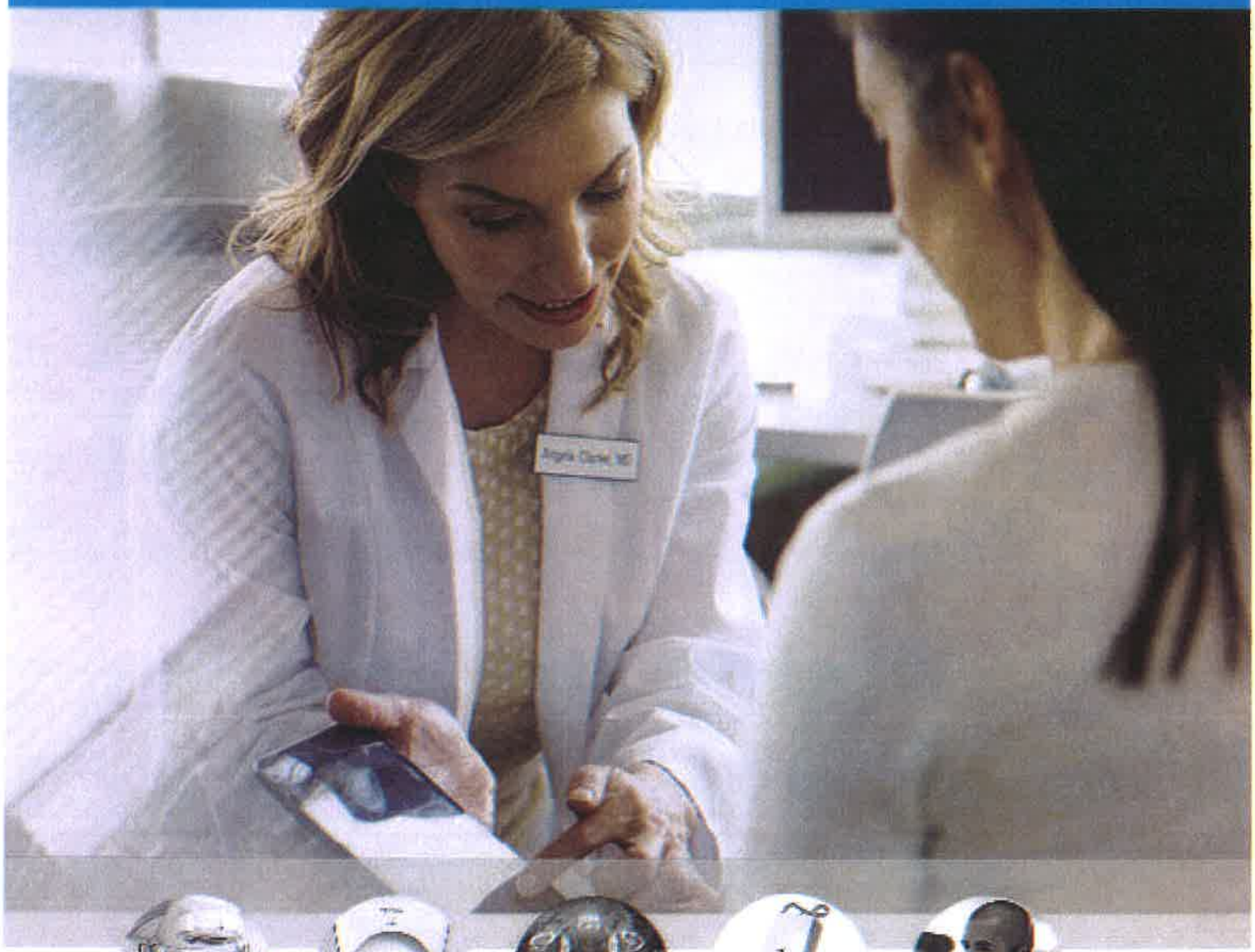
Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			16.75 in. to 21 in. (42.5 cm x 53.3cm) and is only for use in the MR Control Room. Weighs 45 lbs.			
43	1	E8806FA	MR Skull Pins Starter Kit	$33,500.00	21.00%	$26,465.00
	1		**NonProducts**			
44	1		Rigging in iMRI NTE $9999.00	$9,999.00	0.00%	$9,999.00

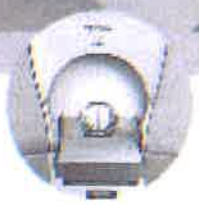
Quote Summary:

Total Contract List Price:	**$6,831,996.14**
Total Discount: (42.04%)	**($2,872,229.47)**
Total Extended Selling Price:	**$3,959,766.67**
Total Quote Net Selling Price	**$3,959,766.67**

(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price Includes Trade In allowance, if applicable.)

ELEKTA





ONCOLOGY | BRACHYTHERAPY | NEUROSCIENCE | SOFTWARE | SERVICES

Elekta is pioneering significant innovations and clinical solutions for treating cancer and brain disorders. We provide intelligent and resource-efficient technologies that improve, prolong and save patient lives.

ELEKTA

Quotation Number: 2015-112631-MB | Quotation Date: October 29, 2015 | Valid Until: January 27, 2016

Prepared For:
Genia Nipp
Methodist Healthcare - Memphis
PO BOX 41058
MEMPHIS, Tennessee 38174-1058
US
(t) (901) 516-0625
(f) (901) 516-0649

Currency: USD

Prepared By:
Donald Wilkymacky
Regional Manager

400 Perimeter Center Terrace Suite 50
Atlanta, GA 30046
(t) (513) 467-6220
(c) +1 5135038287
don.wilkymacky@elekta.com

Elekta is pleased to submit the following Quotation for the products, software licenses, and/or services described herein at the prices and terms stated.

Elekta Versa HD	**Total Products List Price:**	$7,608,958.25
	Total Offer Price:	$2,636,000.00

The price under this Quotation reflects a discount of $4,972,958.25 USD. If customer is an entity that reports its costs on a cost report required by the Department of Health and Human Services or a state healthcare program, the customer must fully and accurately report any discount that has been provided by Elekta under the final agreement between the parties in the applicable cost report and provide information upon request by the Secretary of Health and Human Services or a state agency.A reportable discount may be set out above or exist in the form of undertakings made by Supplier elsewhere in this Agreement.

Subject to Elekta, Inc. Terms and Conditions or those previously negotiated.

State, local, VAT and other taxes, and import/export licenses are not included in this Quotation

B : E(1)(a)(4)
FDA Approvals

SEP 30 2011

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	September 30, 2011
Submitter:	GE Healthcare, (GE Healthcare Japan Corporation) 7-127, Asahigaoka 4-chome, Hino-shi, Tokyo 191-8503 JAPAN
Primary Contact Person:	Toru Shimizu Regulatory Affairs Specialist GE Healthcare, (GE Healthcare Japan Corporation) Telephone: +81-42-585-5344 Fax: +81-42-585-5075
Secondary Contact Person:	Glen Sabin Regulatory Affairs Director GE Healthcare, (GE Medical Systems, LLC) Telephone: (262) 521-6848 Fax: (262) 521-6439
Device: Trade Name:	Discovery MR750w 3.0T
Common/Usual Name:	Magnetic Resonance Imaging System
Classification Names: Product Code:	Magnetic resonance diagnostic device LNH
Predicate Device(s):	Discovery MR750 (K081028) Optima MR450w (K091536)
Device Description:	The Discovery MR750w 3.0T features a superconducting magnet operating at 3.0 Tesla. The data acquisition system accommodates up to 32 independent receive channels in various increments, and multiple independent coil elements per channel during a single acquisition series. The system uses a combination of time-varying magnetic fields (gradients) and RF transmissions to obtain information regarding the density and position of elements exhibiting magnetic resonance. The RF technology of the Discovery MR750w system integrates an RF transmit architecture designed to improve the overall image uniformity. This technology, called Multi-drive, optimizes RF transmit by adjusting the amplitude and phase of the RF output depending on the anatomy being scanned. In order to support Multi-Drive, the RF Transmit (Tx) chain is changed from

MR750 and both Tx lines are divided into 2 lines with Dual output Exciter, Dual output RF amp, Dual Transmit/Receive Switch (DTRSW), dual UPM and a 70cm-wide patient bore RF body coil.

The system can image in the sagittal, coronal, axial, oblique and double oblique planes, using various pulse sequences and reconstruction algorithms. The Discovery MR750w 3.0T is designed to conform to NEMA DICOM standards (Digital Imaging and Communications in Medicine).

Intended Use: The Discovery MR750w 3.0T is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used. The images produced by the Discovery MR750w 3.0T reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Technology: The Discovery MR750w 3.0T employs the same fundamental scientific technology as its predicate devices of Discovery MR750 and Optima MR450w. Refer to Section 12 for details of the Technical Comparison Table and the Application/Feature Comparison Chart.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:
As stated in the FDA document "Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" the following parameters have been measured and documented through testing to NEMA, IEC or ISO standards as referenced throughout this submission and listed in Section 9:

Performance:

- Signal-to-noise ratio (SNR)
- Geometric distortion
- Image uniformity
- Slice thickness
- Spatial resolution

Safety:

- Static field strength
- Acoustic noise
- dB/dt
- RF heating (SAR)
- Biocompatibility

The tests outlined above have been executed with acceptable results. Refer to Section 15, 18 of this submission for the above performance and safety testing results.

The Discovery MR750w 3.0T has been designed to comply with applicable IEC standards as reference to Section 9, 17.

The device has been tested by a Nationally Recognized Testing Laboratory and certified to conform to applicable IEC, UL and CSA standards prior to commercialization of the system.

Numerical simulations were conducted to demonstrate the safety of the Multi-Drive RF transmit system.

The following quality assurance measures were applied to the development of the system as reference to Section 11, 16, 18:

- Risk Analysis and control
- Requirements Reviews
- Design Reviews
- Design Verification
- Performance and Safety testing (Verification)

Summary of Clinical Tests:

Clinical images and clinical results summary demonstrate that the Discovery MR750w 3.0T maintains the same imaging performance results as the predicate systems of Discovery MR750, Optima MR450w. Refer to Section 20 for details of the studies performed.

Conclusion: GE Healthcare considers the Discovery MR750w 3.0T to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Toru Shimizu
Regulatory Affairs Specialist
GE Healthcare Japan Corporation
7-127, Asahigaoka 4-Chrome
Hino-Shi, Tokyo, 191-8503
JAPAN

SEP 30 2011

Re: K103327
Trade/Device Name: Discovery MR750w 3.0T System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LNI and MOS
Dated: September 2, 2011
Received: September 7, 2011

Dear Mr. Shimizu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K103327

510(k) Number (if known): K103327

Device Name: Discovery MR750w 3.0T

Indications for Use:

The Discovery MR750w 3.0T is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used. The images produced by the Discovery MR750w 3.0T reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k)_____

AUG 1 2 2005

K051932

510(k) SUMMARY

Date of preparation of summary:
4th July 2005

Submitted by:
Elekta Limited
Linac House, Fleming Way
Crawley, West Sussex
RH20 9RR
United Kingdom

Contact name, (application correspondent):
Peter Stegagno, Director, Regulatory Affairs & Quality Assurance
4775 Peachtree Industrial Boulevard, Building 300, Suite 300
Norcross, Georgia, 30092
USA

Email: peter.stegagno@elekta.com
Telephone: (770) 300 9725 x2548 Fax: (770) 448 6338

Trade Name:..... Elekta Synergy®, Elekta Synergy® S, and XVI R3.5

Common Name: Medical Linear Accelerator (with Patient Imaging)

Classification Name: Medical Linear Accelerator Accessory 90 IYE

Predicate Device: Elekta Synergy® System (K032996)

Product Description:
This Premarket Notification Special 510(k) describes modifications to the Elekta Synergy® System; a combination of the specially prepared Elekta medical linear accelerator, Elekta Synergy® Platform, with the XVI on-board kV imaging accessory. The primary reasons for the modifications to this product are to provide:

- Hardware & software support for increased patient throughput
- Easier selection of parameters & provision of clinical presets to improve efficiency
- Improved image quality and image management
- Improved tools for device set-up and image processing
- Improved connectivity with other systems through DICOM

Intended Use Statement:
This is unchanged from the predicate device and is defined as;
"The Elekta Synergy®, Elekta Synergy® S, and XVI R3.5
are intended to be used for radiation therapy treatment of malignant neoplastic diseases, as determined by a licensed medical practitioner."

Summary of Technological Characteristics:
The Elekta Synergy® and Elekta Synergy® S comprise a standard Elekta medical linear accelerator, modified to accept the fitting of a kV imaging system (XVI R3.5), with a common MV and kV isocentre and orthogonal beam paths, all as previously cleared under Control Number K032996.

There has been no change made to the underlying technological characteristics of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 2005

Elekta Limited
% Mr. Peter Stegagno
Director, Regulatory Affairs
& Quality Assurance
Elekta, Inc.
4775 Peachtree Industrial Boulevard
Building 300, Suite 300
NORCROSS GA 30092

Re: K051932
Trade/Device Name: Elekta Synergy®, Elekta Synergy® S and XVI R3.5
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 8, 2005
Received: July 13, 2005

Dear Mr. Stegagno:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051932

Device Name ..... Elekta Synergy®, Elekta Synergy® S, and XVI R3.5

Indication for Use: The Elekta Synergy®, Elekta Synergy® S, and XVI R3.5 are intended to be used for radiation therapy treatment of malignant neoplastic diseases, as determined by a licensed physician.

Prescription Use - YES AND/OR Over-The-Counter Use - NO
(Per 21 CFR 801.109 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051932

Elekta Limited, Fleming Way, Crawley, West Sussex, RH10 9RR UK +44 1293 544422 Fax: +44 1293 664321

MAR 0 5 2014

PHILIPS

K133292
Page 1 of 3

510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared:	January 27, 2014	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 4-6 5684-PC, Best, The Netherlands Establishment Registration Number: 3003768277	
Contact:	Mr. Klien van Dam, PhD Regulatory Affairs Manager +3140 2795225	
Device Trade Names:	Allura Xper FD series Allura Xper OR Table series	
Classification	Classification Name:	Image-intensified fluoroscopic X-ray system
	Classification Regulation:	21 CFR 892.1650
	Classification Panel:	Radiology
	Device Class:	II
	Primary product code:	OWB
	Secondary product code	JAA
Predicate Device #1	Device Name	AlluraClarity Xper FD series X-ray system
	Manufacturer	Philips Medical Systems Nederland B.V.
	510(k) number	K130638
	Classification Regulation	21 CFR 892.1650
	Device Class:	II
	Product Code:	OWB
Predicate Device #2	Device Name	Allura Xper FD OR Tables Series
	Manufacturer	Philips Medical Systems Nederland B.V.
	510(k) number	K102005
	Classification Regulation	21 CFR 892.1650
	Device Class:	II
	Product Code:	Primary code: OWB Subsequent code: JAA

Device Description: The Allura Xper family consists of the Allura Xper FD series and the Allura Xper OR Table series and is identified as Allura Xper FD R8.2. The Allura Xper FD R8.2 is a modular angiographic X-ray system, based on a set of components that can be combined into different single and biplane configurations to provide specialized angiography. Combined with a qualified, compatible OR table, the Allura Xper FD R8.2 can also be used for imaging in the Hybrid OR. The Allura Xper FD R8.2 is optionally provided with ClarityIQ technology, which utilizes the advanced XRES4 noise reduction algorithms to reduce quantum noise in X-ray images.

PHILIPS

Indications for Use:

The Allura Xper series and the Allura Xper OR Table series (within the limits of the used OR table) are intended for use on human patients to perform:

- Vascular, cardiovascular and neurovascular imaging applications, including diagnostic, interventional and minimally invasive procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography, as well as PTAs, stent placements, embolisations and thrombolysis.
- Cardiac imaging applications including diagnostics, interventional and minimally invasive procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology (EP).
- Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.

Additionally:

- The Allura Xper and Allura Xper OR Table series is compatible with a hybrid Operating Room.
- Allura Xper FD10 is compatible with specified magnetic navigation systems.
- Combined with a qualified, compatible OR table, the Allura Xper OR Table series can be used for imaging in the Hybrid OR within the applications domains Neuro, Vascular, Non Vascular and Cardiac. The OR table can also be used standalone for surgical use in the OR.

Technology:

The Allura Xper FD R8.2 has the same technological characteristics compared to the predicate devices. Modifications implemented in the Allura Xper FD R8.2 include the introduction of a new, state of the art FD20 X-ray detector with passive cooling, and a higher DQE. Additionally, a new high voltage X-ray generator with reduced size is introduced.

Based on the information provided in this premarket notification, the Allura Xper FD R8.2 is considered substantially equivalent to the currently marketed and predicate devices in terms of:

- Design and functionality
- Indications for use
- Fundamental Scientific Technology
- Performance specifications and testing

Non-clinical Performance Data:

The Allura Xper R8.2 complies with the following international and FDA recognized consensus standard and FDA Guidance Documents:

- IEC 60601-2-43,
- IEC 60601-2-28,
- ISO 14971:
- IEC 62304,
- FDA Guidance document entitled, "Guidance for the

Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005.

- FDA Guidance document entitled, "General Principals of software Validation; Final Guidance for Industry and FDA Staff" issued January 11, 2002.
- FDA Guidance document entitled, "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" issued August 6, 1999.

The test results demonstrate that the Allura Xper FD R8.2:

- Complies with the aforementioned international and FDA-recognized consensus standards and/or FDA guidance documents
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, the Allura Xper FD R8.2 is substantially equivalent to the currently marketed and predicate devices in terms of safety and effectiveness.

Clinical Performance Data: The subject of this premarket submission, the Allura Xper FD R8.2, did not require clinical studies to support substantial equivalence. Sample clinical images that demonstrate diagnostic quality of the images are provided.

Conclusion: The Allura Xper FD R8.2 is substantially equivalent to the predicate devices in terms of design features, fundamental scientific technology, indications for use and safety and effectiveness. The changes implemented in the Allura Xper FD R8.2 System do not render the system to be Not Substantial Equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 5, 2014

Philips Medical Systems Nederland B.V.
% Klien van Dam, Ph.D.
Veenpluis 4-6
5684 PC Best
THE NETHERLANDS

Re: K133292
Trade/Device Name: Allura Xper FD series; Allura Xper OR Table series
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: II
Product Code: OWB, JAA
Dated: January 27, 2014
Received: February 7, 2014

Dear Dr. van Dam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133292

Device Name
Allura Xper series and Allura Xper OR Table series

Indications for Use *(Describe)*
The Allura Xper series and the Allura Xper OR Table series (within the limits of the used OR table) are intended for use on human patients to perform:
• Vascular, cardiovascular and neurovascular imaging applications, including diagnostic, interventional and minimally invasive procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography, as well as PTAs, stent placements, embolisations and thrombolysis.
• Cardiac imaging applications including diagnostics, interventional and minimally invasive procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology (EP).
• Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.

Additionally:
• The Allura Xper and Allura Xper OR Table series is compatible with a hybrid Operating Room.
• Allura Xper FD10 is compatible with specified magnetic navigation systems.
• Combined with a qualified, compatible OR table, the Allura Xper OR Table series can be used for imaging in the Hybrid OR within the applications domains Neuro, Vascular, Non Vascular and Cardiac. The OR table can also be used standalone for surgical use in the OR.

Type of Use *(Select one or both, as applicable)*

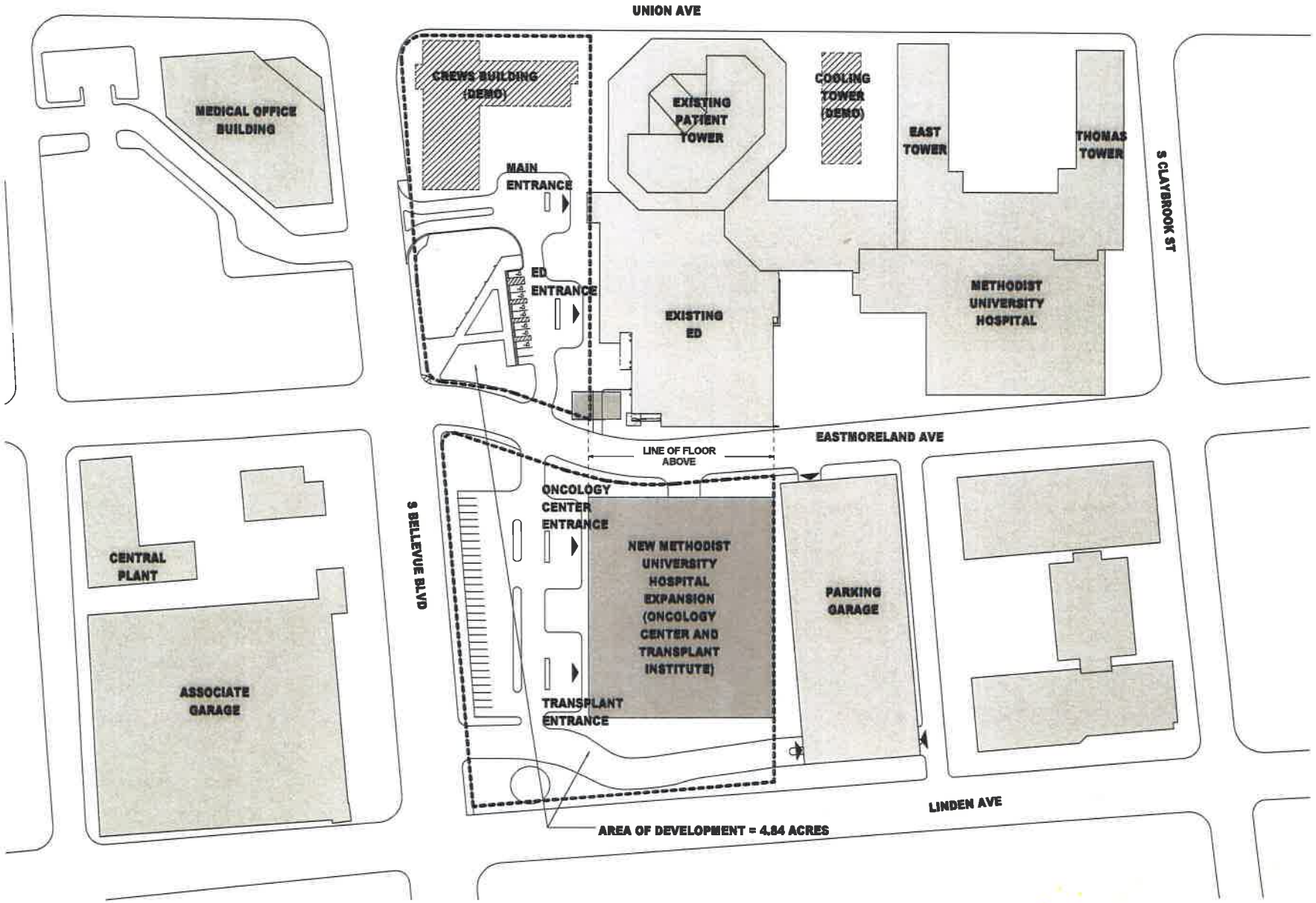
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

B: III (A) Plot Plan



DRAFT

HKS

CLIENT
METHODIST LEBONHEUR HEALTHCARE
6004 CLUB PARKWAY
COLLIERVILLE, TN 38017

ARCHITECT
HKS, INC.
350 N SAINT PAUL ST SUITE 100
DALLAS, TX 75201-4240

ASSOCIATE ARCHITECT
SELF - TUCKER ARCHITECTS
800 TENNESSEE STREET SUITE 101
MEMPHIS, TN 38103

INTERIOR DESIGN
HKS, LLC
350 N SAINT PAUL ST SUITE 100
DALLAS, TX 75201-4240

MEP ENGINEER
TME
1 ALLIED DRIVE, SUITE 2022
LITTLE ROCK, AR 72202

STRUCTURAL
ALLEN & HOSHALL
1661 INTERNATIONAL DRIVE SUITE 100
MEMPHIS, TN 38120

CIVIL ENGINEER
ALLEN & HOSHALL
1661 INTERNATIONAL DRIVE SUITE 100
MEMPHIS, TN 38120

LANDSCAPE ARCHITECT
MACK MCGINNIS ASSOCIATES
5865 POPLAR AVENUE SUITE 1100
MEMPHIS, TN 38119

METHODIST UNIVERSITY HOSPITAL

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Issued
Rev #
Date

KEY PLAN

REVISIONS
NO. DESCRIPTION DATE

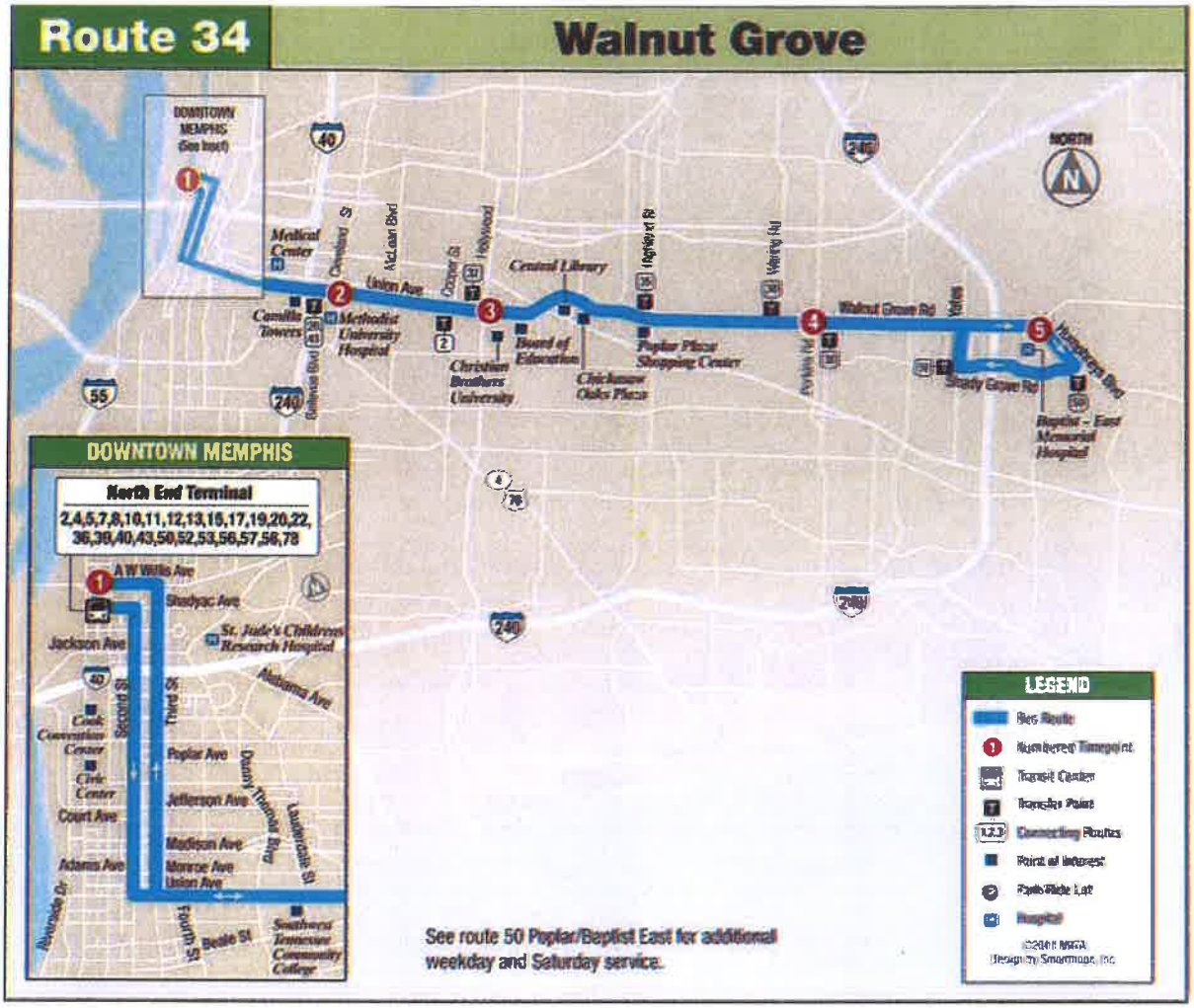
HKS PROJECT NUMBER
19715.000
DATE
JANUARY 29, 2016
ISSUE
CON - FINAL DRAFT

SHEET TITLE
SITE PLAN

SHEET NO.
A1.0

B: III (B)
Road Maps and Public Transportation Route

Route 34 Walnut Grove



MONDAY – FRIDAY • OUTBOUND FROM DOWNTOWN

	1 North End Terminal	2 Union Ave at Cleveland St	3 Union Ave at Hollywood	4 Walnut Grove at Perkins Rd	5 Humphreys Blvd at Walnut Grove
AM	5:54	6:07	6:17	6:27	6:40
	6:40	6:53	7:03	7:13	7:26
	7:31	7:44	7:54	8:04	8:17
	8:17	8:30	8:40	8:50	9:03
	9:08	9:21	9:31	9:41	9:54
	10:45	10:58	11:08	11:18	11:31
PM	12:25	12:38	12:48	12:58	1:11
	2:05	2:18	2:28	2:38	2:51
	2:50	3:03	3:13	3:23	3:36
	3:42	3:55	4:05	4:15	4:28
	4:28	4:41	4:51	5:01	5:14
	5:19	5:32	5:42	5:52	6:05

MONDAY – FRIDAY • INBOUND TO DOWNTOWN

	5 Humphreys Blvd at Walnut Grove	4 Walnut Grove at Perkins Rd	3 Union Ave at Hollywood	2 Union Ave at Cleveland St	1 North End Terminal
AM	6:43	6:58	7:08	7:18	7:31
	7:29	7:44	7:54	8:04	8:17
	8:20	8:35	8:45	8:55	9:08
	9:06	9:21	9:31	9:41	9:54
	9:57	10:12	10:22	10:32	10:45
	11:34	11:49	11:59	12:09	12:25
PM	1:14	1:29	1:39	1:49	2:05
	2:54	3:09	3:19	3:29	3:42
	3:40	3:55	4:05	4:15	4:28
	4:31	4:46	1304:56	5:06	5:19
	5:17	5:32	5:42	5:52	6:05

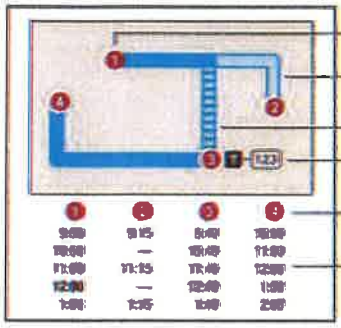
SATURDAY • OUTBOUND FROM DOWNTOWN

	1 North End Terminal	2 Union Ave at Cleveland St	3 Union Ave at Hollywood	4 Walnut Grove at Perkins Rd	5 Humphreys Blvd at Walnut Grove
AM	6:08	6:13	6:23	6:33	6:46
	7:38	7:51	8:01	8:11	8:24
	9:15	9:28	9:38	9:48	10:01
	10:52	11:05	11:15	11:25	11:38
PM	12:30	12:43	12:53	1:03	1:16
	2:10	2:23	2:33	2:43	2:56
	3:47	4:00	4:10	4:20	4:33
	5:25	5:38	5:48	5:58	6:11

SATURDAY • INBOUND TO DOWNTOWN

	5 Humphreys Blvd at Walnut Grove	4 Walnut Grove at Perkins Rd	3 Union Ave at Hollywood	2 Union Ave at Cleveland St	1 North End Terminal
AM	6:50	7:05	7:15	7:25	7:38
	8:27	8:42	8:52	9:02	9:15
	10:04	10:19	10:29	10:39	10:52
	11:41	11:56	12:06	12:16	12:29
PM	1:19	1:34	1:44	1:54	2:07
	2:56	3:14	3:24	3:34	3:47
	4:36	4:51	5:01	5:11	5:24

INSTRUCTIONS



The bus stops at this location at listed times.
Look for the column of times below the matching symbol in the schedule.

Only certain trips operate along this portion of the route.
See the schedule for trips that provide service here.

The bus operates express along this portion of the route.

Transfer point. Shows where this bus intersects with other routes that are available for transfer.

The bus stops at the times listed below the numbered symbol.
Light times are A.M.; **bold** times are P.M.

The timetable shows when the bus is scheduled to depart.
Actual departure times may vary and depend upon traffic and weather conditions. Arrive at the bus stop about 5 minutes early to avoid missing the bus.

MATA FARES

BASE FARES — EFFECTIVE: JANUARY 4, 2010

Adult Base Fare	$1.50
*City Student Base Fare	$1.20
*County Student Base Fare	$1.40
*Seniors & Individuals w/Disabilities	$0.75
Express Base Fare	$2.10

* MATA ID REQUIRED.

ZONE 1 FARE

Base Fare Plus Additional Zone Fare ..... + $0.75
(See Route Map for Zone Boundaries)

MULTI-RIDE PASSES

Daily FastPass	$3.25
7-Day FastPass	$15.00
31-Day FastPass	$50.00
31-Day Express FastPass	$60.00
*Student Daily FastPass	$2.60
*Student 7-Day FastPass	$12.00
*Student 31-Day FastPass	$40.00
Senior/Disabled Daily FastPass	$1.60
*Senior/Disabled 7-Day FastPass	$7.50
*Senior/Disabled 31-Day FastPass	$25.00
*Senior/Disabled 31-Day Express FastPass	$30.00

* MATA ID REQUIRED. Students in grades 1-12, seniors and people with disabilities must have a valid MATA ID to receive the FastPass at a reduced price. Two forms of identification must be presented to obtain ID at MATA's Customer Service Center. (A Medicare card is a valid form of identification.)

Route schedules may be subject to change without notice.

MATA INFORMATION

American Way Transit Center	
3021 American Way	(901) 722-0322
North End Terminal	
444 N. Main Street	(901) 523-8134
MATA Administrative Offices	
1370 Levee Road	(901) 722-7100
Route and Schedule Information	(901) 274-6282
Lost and Found	(901) 523-8134
Comments, Compliments, Complaints	(901) 522-8175
Main Street Trolley	(901) 577-2640
MATAplus Information	(901) 722-7171
TTY Hearing and Speech Impaired	(901) 523-2017

Large print schedules are available upon request.

Visit us at: www.matatransit.com

(901) 274-6282
www.matatransit.com

MATA

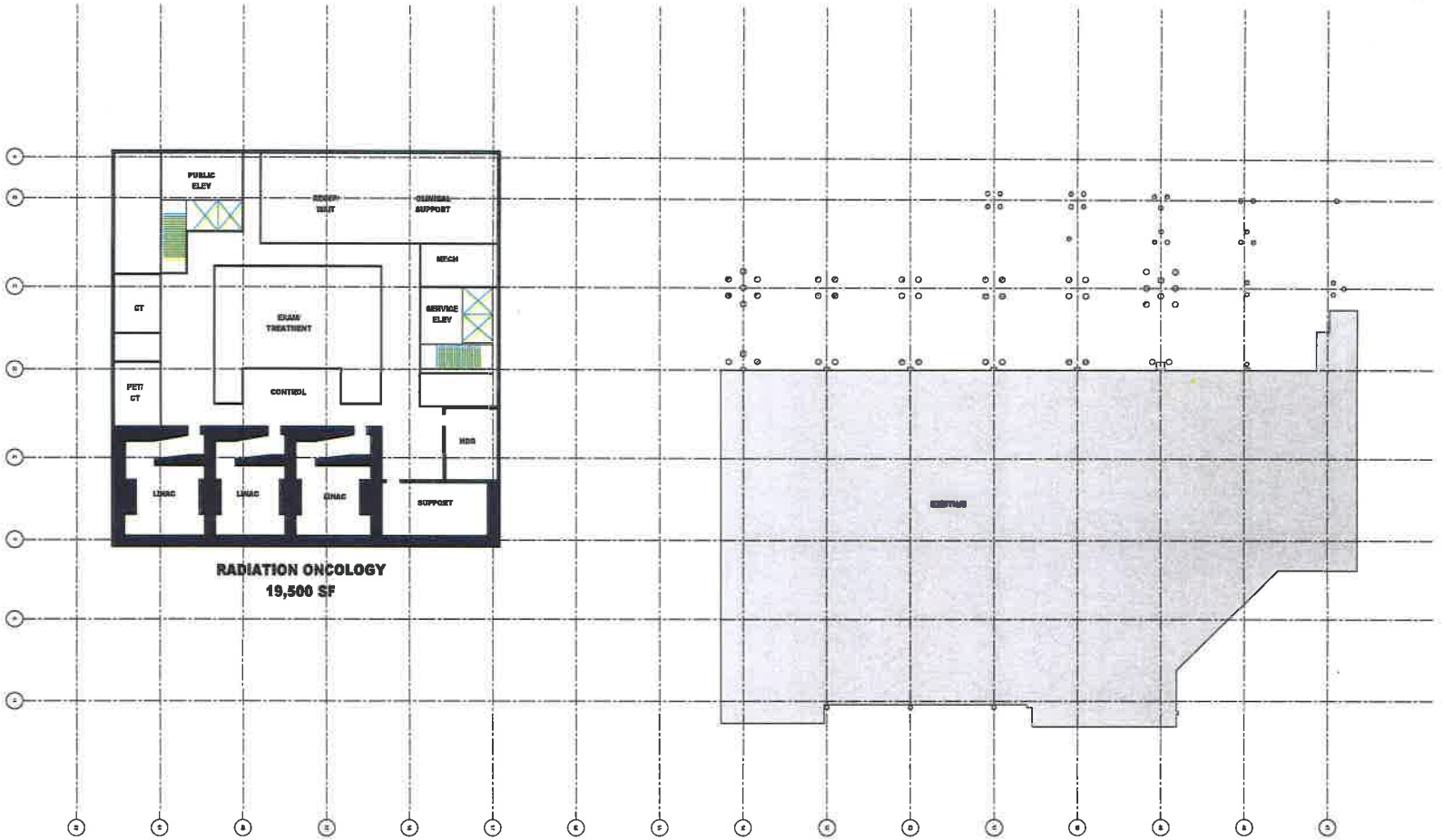
ROUTE 34

Walnut Grove SERVING

- Baptist East Hospital
- Central Library
- Methodist University Hospital
- Southwest TN Community College
- University of Tennessee
- Medical Center
- Downtown Memphis
- North End Terminal

Effective 12/4/11

B: IV Floor Plans



LEVEL 00 - GROUND

N

DRAFT

HKS

CLIENT
METHODIST LEBONHEUR HEALTHCARE
6670 CLIBURN PARKWAY
CORDOVA, TN 38018

ARCHITECT
HKS, INC.
2570 N SAINT PAUL ST. SUITE 140
DALLAS, TX 75201-1365

ASSOCIATE ARCHITECT
SELF - TUCKER ARCHITECTS
100 TID AVENUE STREET, SUITE 101
MEMPHIS, TN 38103

INTERIOR DESIGN
HKS, INC.
2570 N SAINT PAUL ST. SUITE 140
DALLAS, TX 75201-1365

MEP ENGINEER
TME
1 ALLIED DRIVE, SUITE 2100
LITTLE ROCK, AR 72202

STRUCTURAL
ALLEN & HOSHALL
1661 INTERNATIONAL DRIVE, SUITE 600
MEMPHIS, TN 38120

CIVIL ENGINEER
ALLEN & HOSHALL
1661 INTERNATIONAL DRIVE, SUITE 100
MEMPHIS, TN 38120

LANDSCAPE ARCHITECT
EDAW / AECOM USA, INC.
3041 POPLAR AVENUE, SUITE 1500
MEMPHIS, TN 38111

METHODIST LE BONHEUR UNIVERSITY HOSPITAL

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19715.000
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JANUARY 29, 2016
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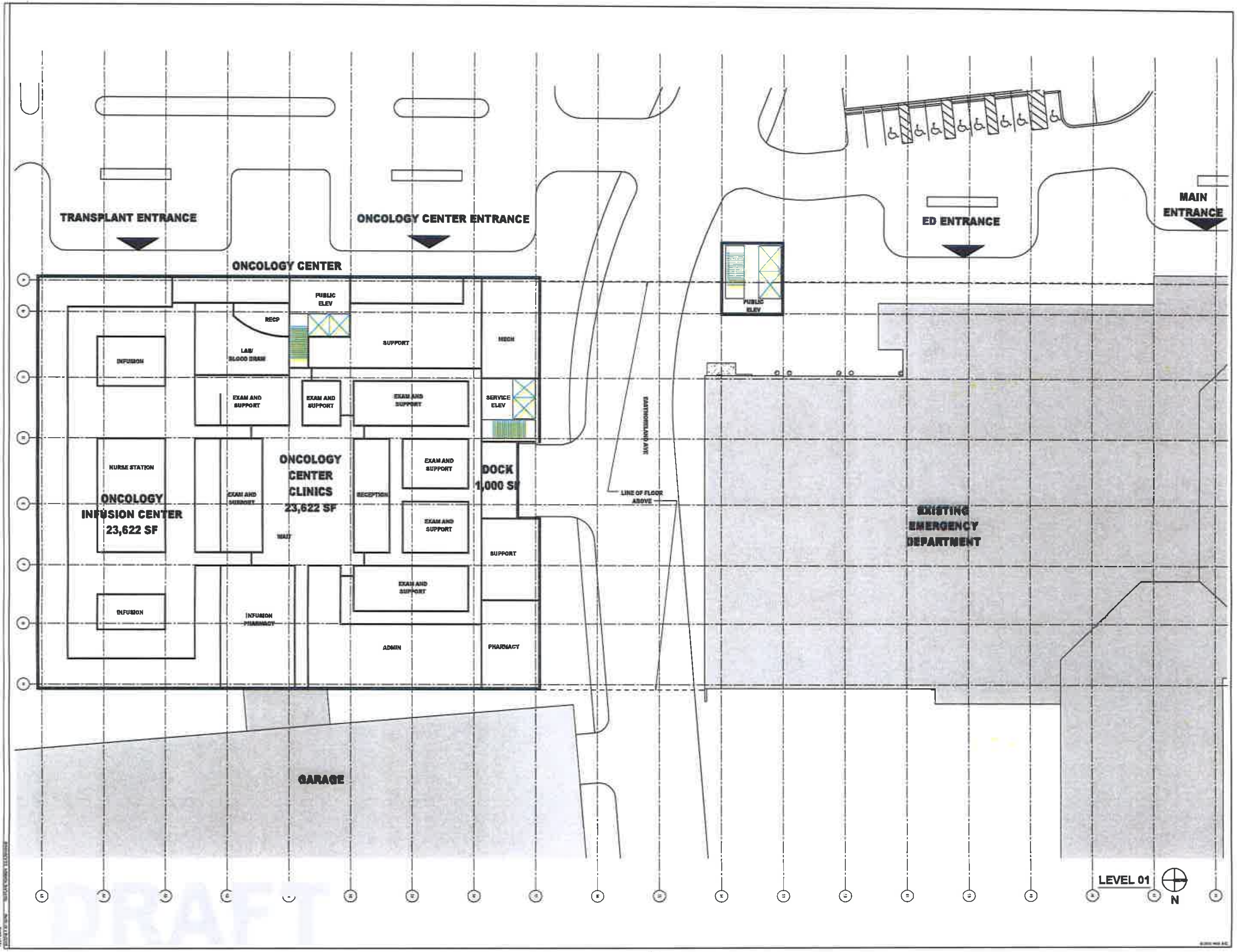
SHEET TITLE
LEVEL 00
GROUND

SHEET NO.
A1.00



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LEVEL 01

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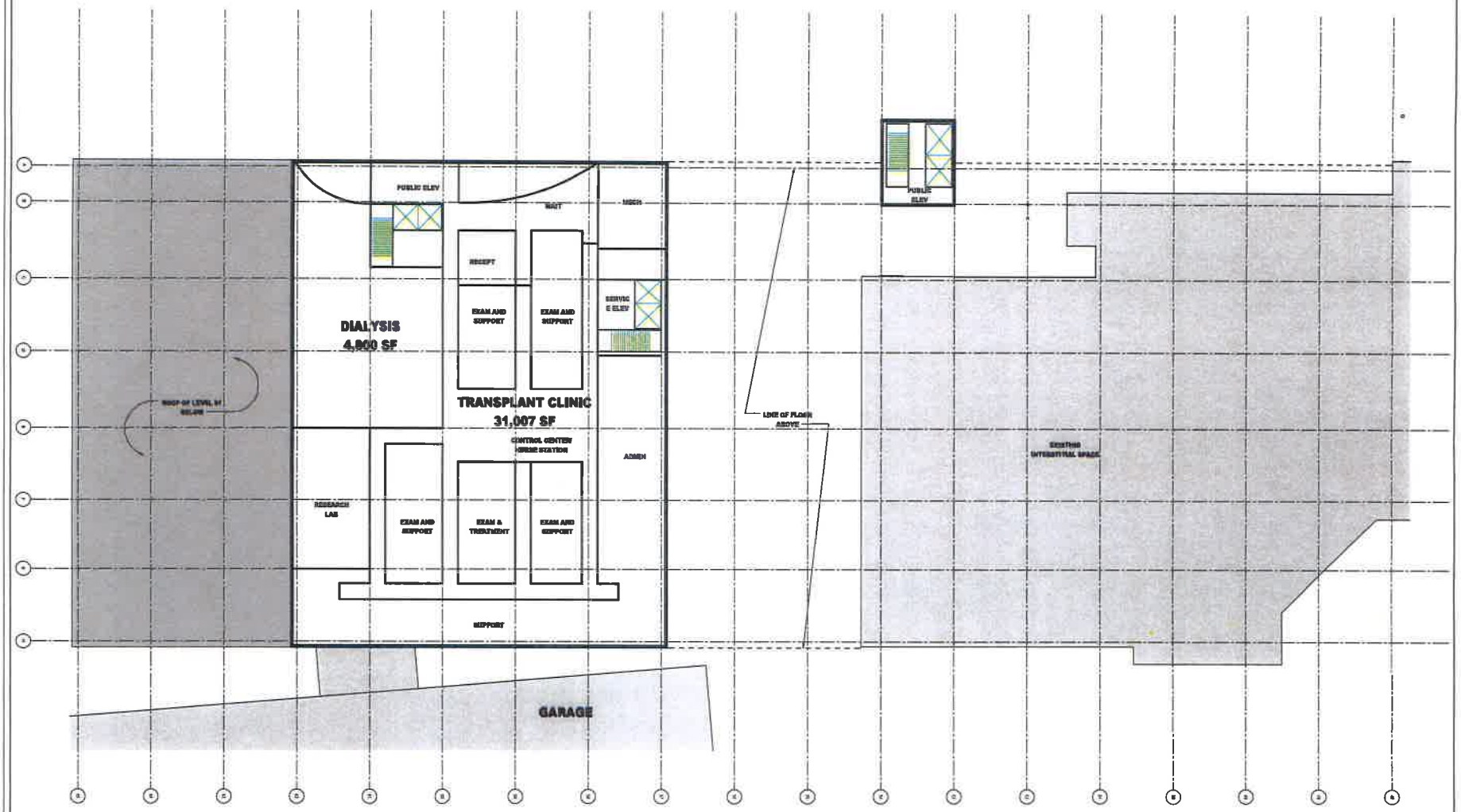

DRAFT

LEVEL 02

N

HKS

CLIENT

ARCHITECT

ASSOCIATE ARCHITECT

INTERIOR DESIGN

MEP ENGINEER

STRUCTURAL

CIVIL ENGINEER

LANDSCAPE ARCHITECT

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19715.000

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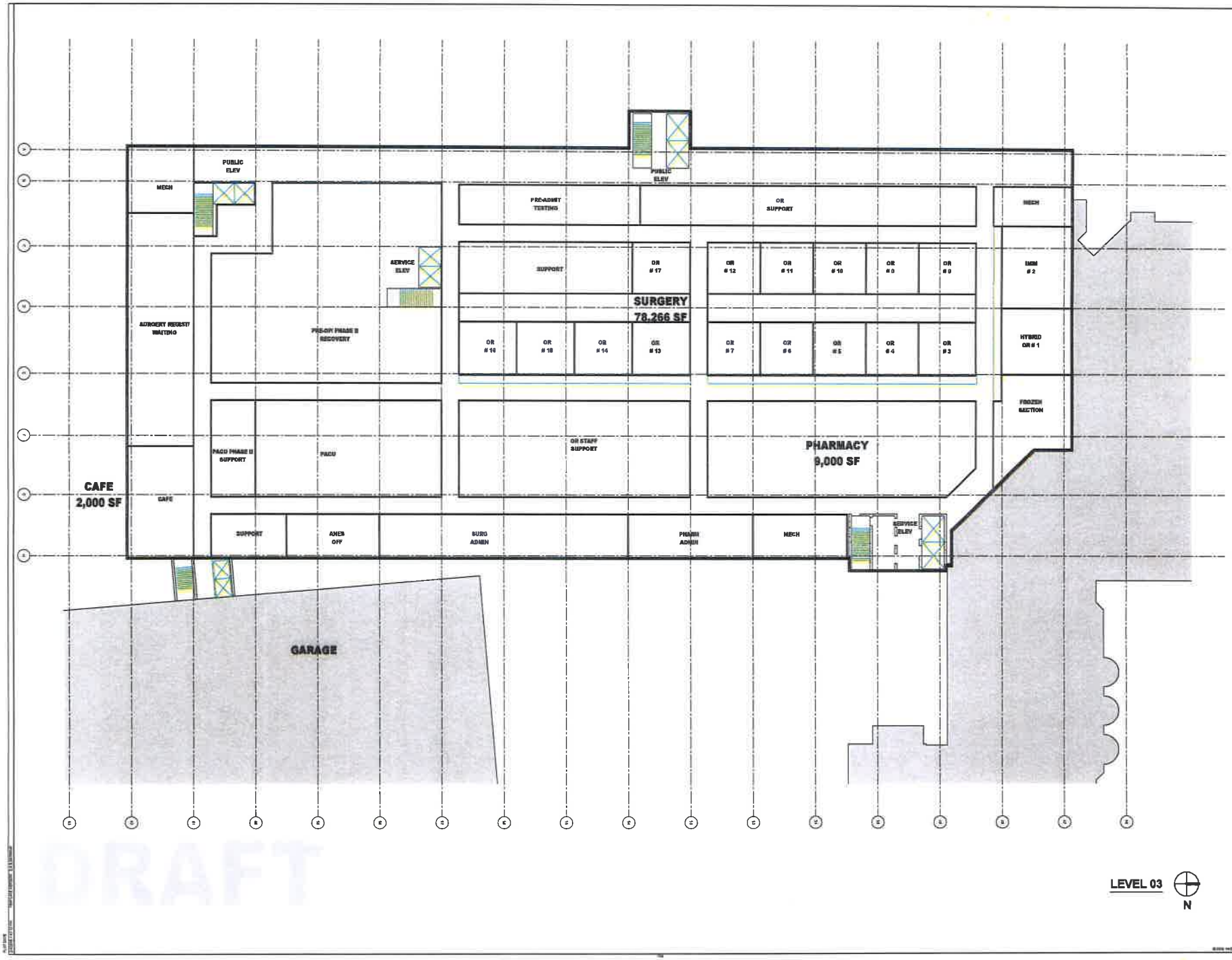

HKS

CLIENT
METHODIST LEBONHEUR HEALTHCARE
6075 CLUB PARKWAY
COLLIERVILLE TN 38017

ARCHITECT
HKS, INC.
350 N SAINT PAUL ST. SUITE 100
DALLAS, TX 75201-4240

ASSOCIATE ARCHITECT
BLA + TUCKER ARCHITECTS
565 TOWNSEND STREET, SUITE 101
MEMPHIS, TN 38103

INTERIOR DESIGN
HKS INC.
350 N SAINT PAUL ST. SUITE 100
DALLAS, TX 75201-4240

MEP ENGINEER
TME
1 ALLIED DRIVE, SUITE 1400
LITTLE ROCK, AR 72202

STRUCTURAL
ALLEN E. MCDONALD
1661 INTERNATIONAL DRIVE SUITE 160
MEMPHIS TN 38120

CIVIL ENGINEER
ALLEN E. MCDONALD
1661 INTERNATIONAL DRIVE SUITE 160
MEMPHIS TN 38120

LANDSCAPE ARCHITECT
MMA HEINTENKAMP ASSOCIATES
5240 POPLAR AVENUE, SUITE 1620
MEMPHIS TN 38157

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Auth. Reg. No.: [illegible]
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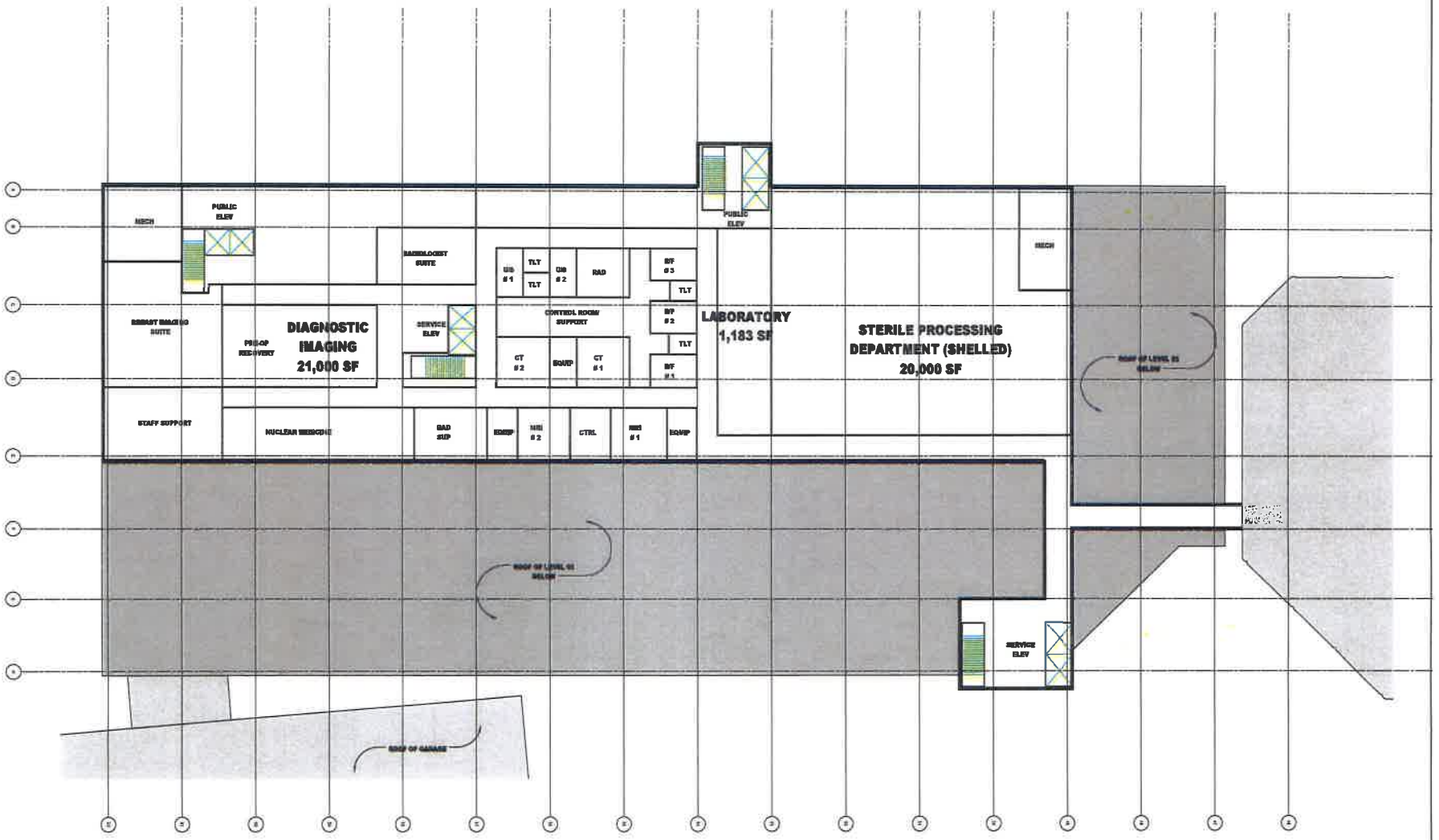

LEVEL 04

N

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HKS

CLIENT
METHODIST LEBONHEUR HEALTHCARE
6670 QUAIL POINTE
CORDOVA, TN 38016

ARCHITECT
HKS, INC.
350 N SAINT PAUL ST, SUITE 100
DALLAS, TX 75201-4240

ASSOCIATE ARCHITECT
SELF + TUCKER ARCHITECTS
165 MADISON STREET, SUITE 101
MEMPHIS, TN 38103

INTERIOR DESIGN
HKS, INC.
350 N SAINT PAUL ST, SUITE 100
DALLAS, TX 75201-4240

MEP ENGINEER
TME
1 ALLIED DRIVE, SUITE 1600
LITTLE ROCK, AR 72202

STRUCTURAL
ALLEN & HOSHALL
1661 INTERNATIONAL DRIVE, SUITE 500
MEMPHIS, TN 38120

CIVIL ENGINEER
ALLEN & HOSHALL
1661 INTERNATIONAL DRIVE, SUITE 500
MEMPHIS, TN 38120

LANDSCAPE ARCHITECT
MACK FEDERSPIEL ASSOCIATES
3960 POPLAR AVENUE, SUITE 1600
MEMPHIS, TN 38111

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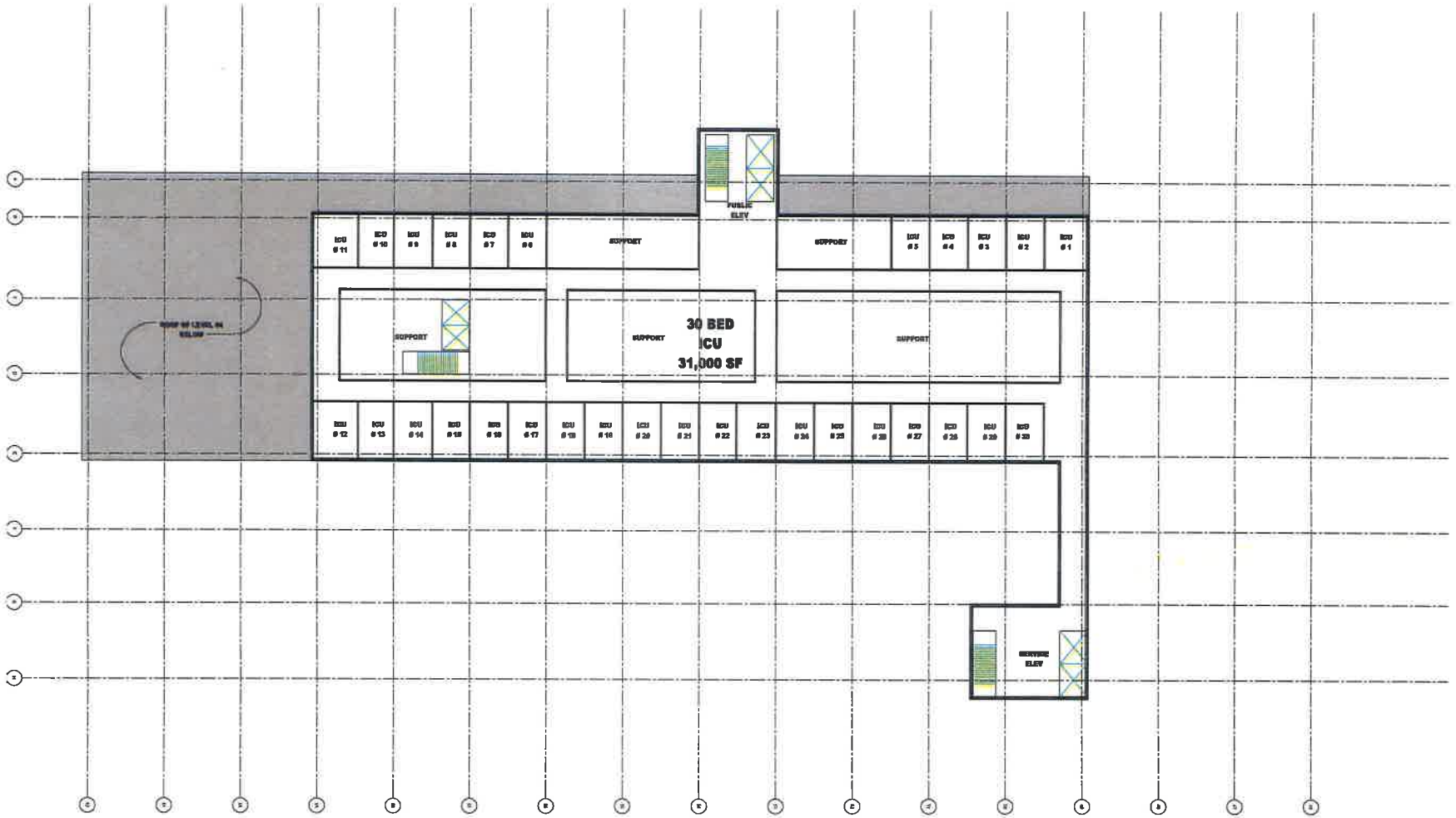

LEVEL 05

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ARCHITECT

ASSOCIATE ARCHITECT

INTERIOR DESIGN

MEP ENGINEER

STRUCTURAL

CIVIL ENGINEER

LANDSCAPE ARCHITECT

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Arch. Reg. #: 30123
Date: 1/29/2016

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10715.000

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LEVEL 06

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ASSOCIATE ARCHITECT

INTERIOR DESIGN

MEP ENGINEER

STRUCTURAL

CIVIL ENGINEER

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LEVEL 06

A1.06

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ASSOCIATE ARCHITECT

INTERIOR DESIGN

MEP ENGINEER

STRUCTURAL

CIVIL ENGINEER

LANDSCAPE ARCHITECT

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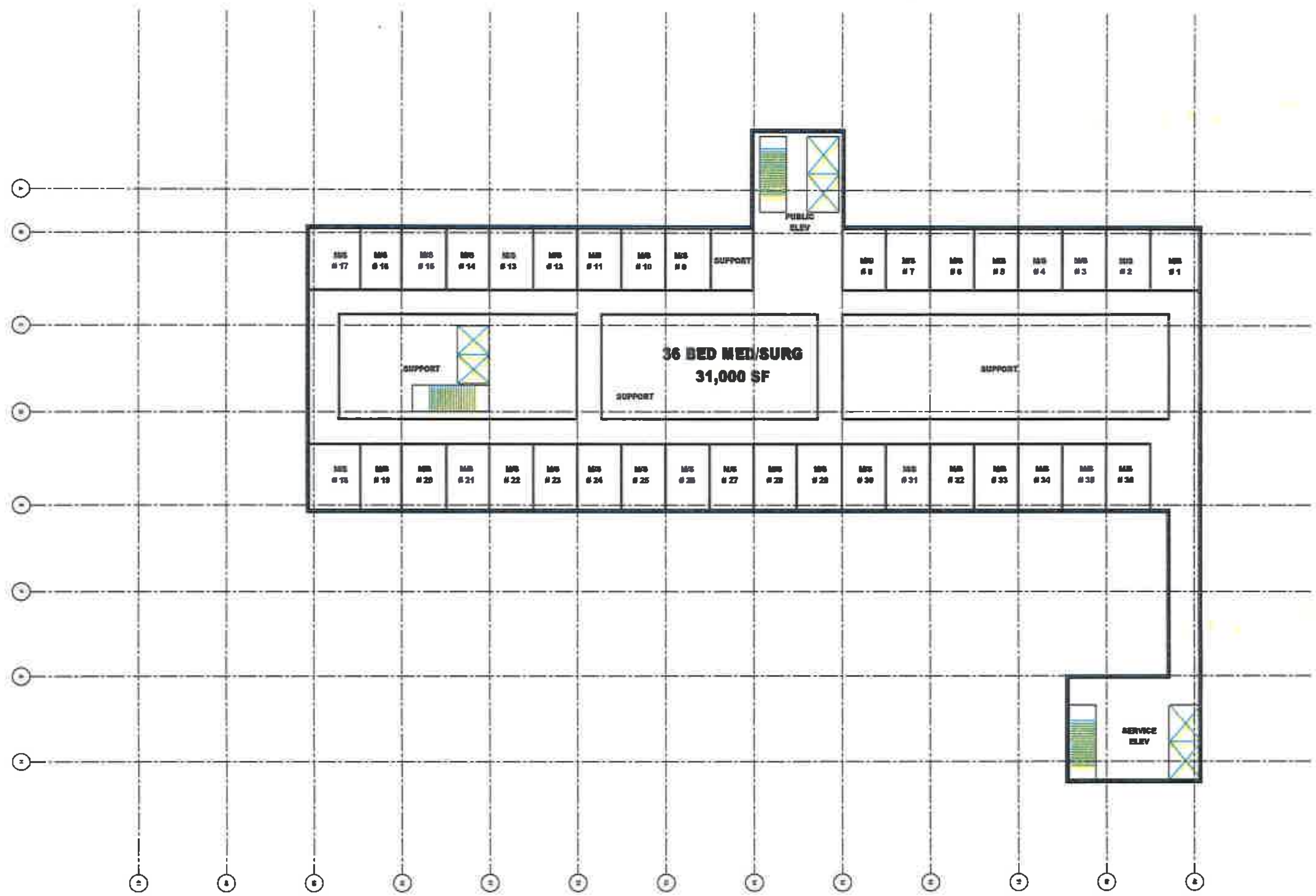

LEVEL 07

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JANUARY 29, 2016

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LEVEL 07

A1.07

LEVEL 08

N

HKS

CLIENT

ARCHITECT

ASSOCIATE ARCHITECT

INTERIOR DESIGN

MEP ENGINEER

STRUCTURAL

CIVIL ENGINEER

LANDSCAPE ARCHITECT

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JANUARY 20, 2016

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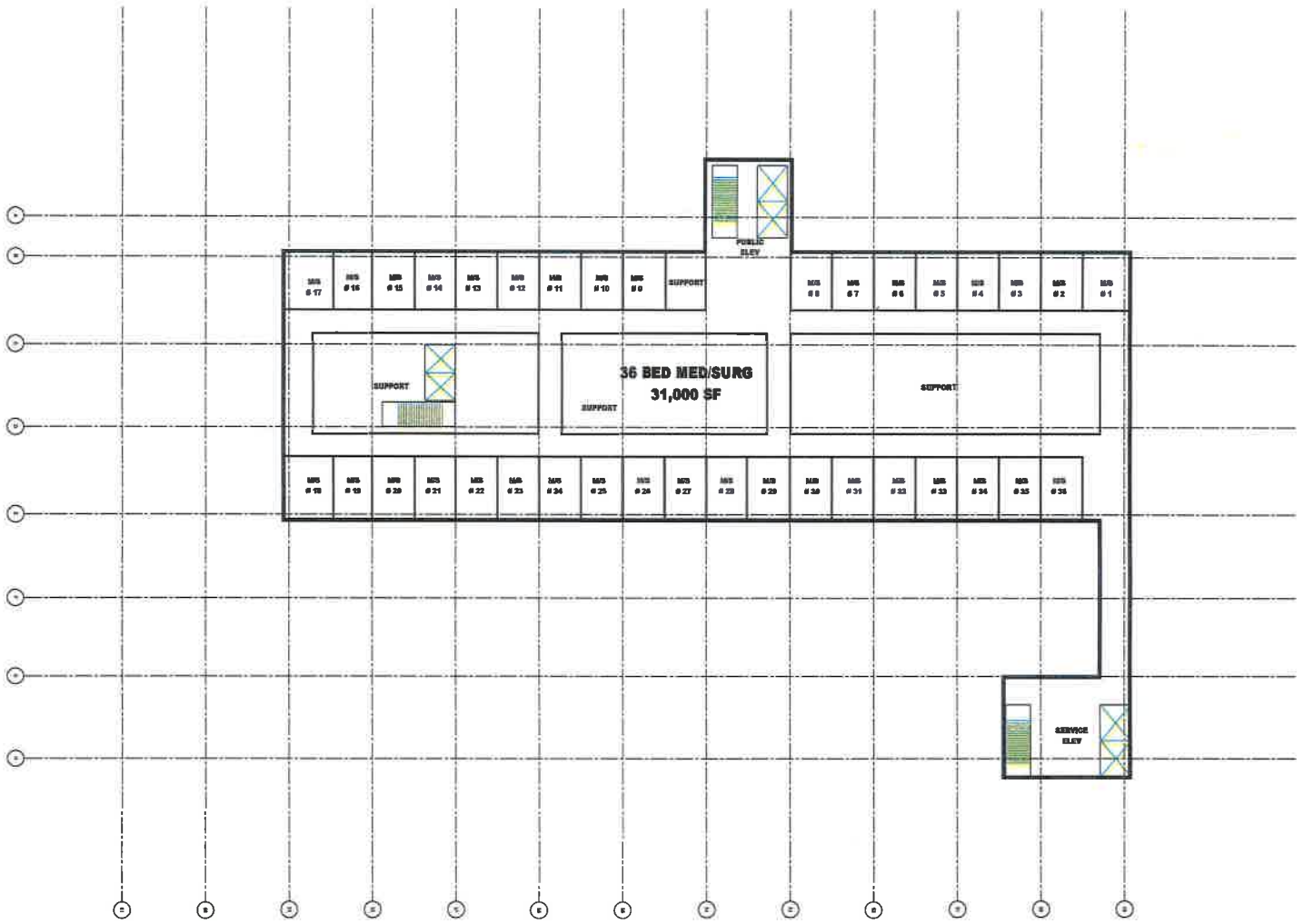
LEVEL 08

A1.08



LEVEL 09

N

HKS

CLIENT

ARCHITECT

ASSOCIATE ARCHITECT

INTERIOR DESIGN

MEP ENGINEER

STRUCTURAL

CIVIL ENGINEER

LANDSCAPE ARCHITECT

METHODIST UNIVERSITY HOSPITAL

INTERIM REVIEW ONLY

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19715.000
DATE
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LEVEL 09

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A1.09

LEVEL 10

N

HKS

CLIENT
METHODIST LEBONHEUR HEALTHCARE
6325 CLEAR PARKWAY
CORDOVA, TN 38016

ARCHITECT
HKS, INC.
350 N SAINT PAUL ST SUITE 100
DALLAS, TX 75201-4240

ASSOCIATE ARCHITECT
GELF + TURNER ARCHITECTS
100 TRADECENT STREET SUITE 101
LEBANON TN 37090

INTERIOR DESIGN
HKS, INC.
350 N SAINT PAUL ST SUITE 100
DALLAS, TX 75201-4240

MEP ENGINEER
TME
1 ALLIED DRIVE, SUITE 2400
LITTLE ROCK, AR 72202

STRUCTURAL
ALLEN & HERSHALL
5001 INTERNATIONAL DRIVE SUITE 100
MEMPHIS TN 38120

CIVIL ENGINEER
ALLEN & HERSHALL
5001 INTERNATIONAL DRIVE SUITE 100
MEMPHIS TN 38120

LANDSCAPE ARCHITECT
RMH ENGINEERING ASSOCIATES
5100 POPLAR AVENUE SUITE 1920
MEMPHIS TN 38137

METHODIST UNIVERSITY HOSPITAL

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JANUARY 29, 2016
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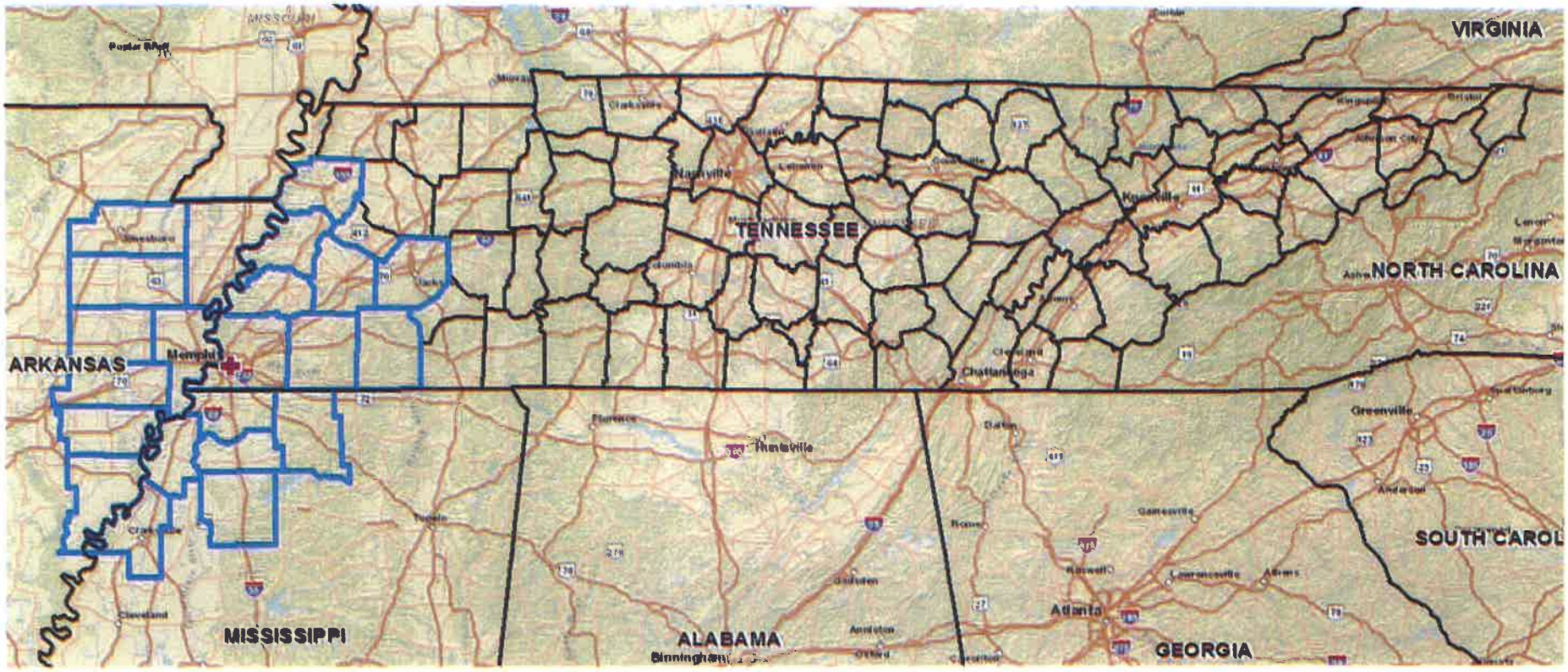
LEVEL 10

SHEET NO.
A1.10

C: Need (3) Service Area Maps

Service Area Map



C: Need PET Criteria (6) (d)
Physician Order Policy

	THIS	REPLACES
INDEX	S-05-051	
REVISED	04/03/06	01/10/06
EFFECTIVE	01/01/01	
PAGE	1 of 2	

SYSTEM POLICY

ORIGINATOR: Administration

SUBJECT: Outpatient Orders for Diagnostic Services

PURPOSE: To establish guidelines under which the medical staff can order outpatient, non-surgical services in a Methodist Healthcare facility.

FUNCTIONS AFFECTED: Patient Access Services (including Scheduling, Patient Registration, Outpatient Care Center), all ancillary service areas, Health Information Management (outpatient record department) and Utilization Review.

POLICY: Methodist Healthcare recognizes that federal legislation placed an affirmative duty on Hospitals and Physicians to document authorization and medical necessity for outpatient diagnostic services. Failure to abide by CMS regulations has serious penalties for providers of healthcare, including the possibility of personal liability for those who do not properly document and code.

All functions affected must work with Medical staff members and referring physicians to ensure that the following guidelines are met prior to procedures being performed:

1. All requests for diagnostic outpatient services (i.e. any test, procedure, treatment or other service) must be accompanied by a **written, signed and dated** Physician order. A Physician or a Nurse Practitioner may submit this signed order. Rubber stamp signatures are not acceptable. In the case of recurrent care outpatient encounters, one order will be valid for 6 months as long as the physician name, treatment regimen and medical necessity documentation remains unchanged.

2. Patients arriving for an outpatient diagnostic service for whom an order has not been sent to Patient Access or the ancillary department prior to the patients' arrival, will be asked to wait or be rescheduled until the order is received by facsimile or other appropriate means.

In order to ensure compliance for our coding and billing functions, this policy will be followed for all payer groups (not just our Medicare patient population).

	THIS	REPLACES
INDEX	S-05-051	
REVISED	04/03/06	01/10/06
EFFECTIVE	01/01/01	
PAGE	2 of 2	

APPROVED:

Peggy Troy
COO, Methodist Healthcare

AUTHORIZED:

Gary S. Shorb
CEO, Methodist Healthcare

C: Need PET Criteria (6) (e) (1)
Medical Director CV

WILLIAM A. GRAVES, M.D.

1557 Peabody Avenue, Memphis, TN 38104
901-276-8814

EXPERIENCE

Radiologist, July 1999 – Present
Memphis Radiological, P.C., Germantown, TN

Assistant Professor – Department of Radiology, June 30, 2012
University of Tennessee, Memphis, TN

EDUCATION/TRAINING

Fellowship – Nuclear Medicine, 2001
Duke University, Durham, NC

Residency – Radiology, 1995-1999
Methodist Hospitals of Memphis, Memphis, TN

Internship - 1994-1995
Methodist Hospitals of Memphis, Memphis, TN

Medical School, 1994
University of Mississippi School of Medicine, Jackson, MS

Undergraduate – B.S., 1990
Mississippi College, Clinton, MS

PROFESSIONAL MEMBERSHIPS

Radiologic Society of North America
American Roentgen Ray Society
Society of Nuclear Medicine

LICENSURE/CERTIFICATION

Tennessee – MD0000029116
Mississippi - 15289
American Board of Radiology, 1999
CAQ Nuclear Radiology

C: Need PET (6) (e) (2)
Medical Director's Responsibilities

Nuclear Medicine/
Positron Emission Tomography Department
Medical Director

Job Summary:

The medical director leads the clinical operations of the Nuclear Medicine/Positron Emission Tomography department. The primary roles are:

1. Developing, with administration and department management, annual and long-term department goals and objectives.
2. Organizing and monitoring the quality of clinical operations.
3. Balancing clinical quality and economic efficiency according to the hospital and health care system goals.

As an integral member of the department's management team, the Medical Director has full access to all information related to the operation of the department. The Medical Director entrusts to the department management those issues not directly related to the clinical aspects of the department. The department management conversely consults the Medical Director on important clinical issues. By virtue of this relationship, the medical director generally may allot the bulk of his or her time to clinical care and rely on department management and teams for day-to-day operations.

The hospital and/or health care system provides the medical director reasonable facilities, tools and staff to fulfill the outlined duties.

I. Duties and Responsibilities:

Essential Functions

1. Quality and Regulatory

   A. Development and implementation of department continuous quality improvement. This activity includes:

   - Participating in quality planning for the department.
   - Actively participating in redesign of care processes that reduce errors. Eliminate unnecessary variation and close the gap between knowledge and practice.
   - Directing the utilization of evidence-based practice within the department and adapting best practices as appropriate to Methodist Le Bonheur Healthcare (MLH).
   - Focusing on data-driven outcome management.
   - Participating in the review and revision of coordination of care processes across patient conditions, services and settings.

- Participating in and promoting the effective use of information technology among the clinical staff.

B. Actively participate and support System Quality Improvement initiatives.

- Assist hospital management with all preparation for any inspections and on-site surveys conducted by governmental agencies or accrediting organizations, including JCAHO and other specialty accreditations, as appropriate. Fulfillment of this responsibility means that the department will meet the requirement of an inspection at any time.
- Actively participate in the establishment of goals and continuous monitoring of patient satisfaction data for department

C. Support the medical management process in assuring appropriate use of resources.

2. Operations

A. Participate actively in the development and implementations of cost alignment in the department.
B. Assess department performance reports and indicators with administration on a regular basis. Indicators will address department specific quality, service, patient satisfaction and financial indicators.
C. Participate in timely evaluation of Department Director and other departmental associates, as appropriate.
D. Assist with facilitating smooth integration of the medial aspects of the department services with other hospital and/or health system services.
E. Provide ongoing assessment and recommendations for upgrades, replacement or removal of the department's clinical equipment and technology, in conjunction with management.
F. Work with hospital administration to provide medical expertise when necessary.
G. Periodically review department clinical policies. Pursue appropriate feedback regarding department policies and procedures, when necessary.
H. Collaborate with the manager in assessing and recommending off-site resources or needed patient care services not provided by the department, hospital or health system.

3. Staffing

A. Plan appropriate physician workforce of the department as evidenced by good accessibility of physicians and reasonable response times to patients, families, referring physicians and payers.
B. Prepare other physicians to serve as qualified designee in his/her absence and inform medical administration of the designee.

C. Recommend annual continuing education goals for the clinical staff (in compliance with state and national regulations).
D. Attend department staff meetings and help establish times and dates.

4. **Planning and Business Development**

A. Assist administration and department management with the development of annual department operating goals, objectives and budgets.
B. Participate actively in sessions focused on new business/program development for the department.
C. Participate in local and regional marketing initiatives. Participate in the planning and implementation of regional clinics.

II. Other Important Functions

1. Attends scheduled Medical Directors' meetings.
2. Participates in an annual performance review of goals and achievements.
3. Participate in media training as planned by MLH.

III. Organizational Relationships

The Medical Director reports clinically to the Chief Medical Officer and the Medical/Dental Staff structure on clinical issues. He/she collaborates closely with department management and the appropriate hospital Vice President on administrative and general issues. Within the relationship, the Medical Director relies on the department management to implement administrative decisions, such as employee actions, commitment of hospital resources, etc.

IV. Qualification - Education and Experience

- Board certified in Nuclear Medicine or Diagnostic Radiology with additional training and experience required to perform duties as assigned.
- A member in good standing at all times of the MLH Medical Staff.
- Participation in continuing education and informational meetings required to maintain current skills in his or her capability as Medical Director.

V. STATEMENT OF NONINCLUSIVITY:

This job description is not to be construed as a complete listing of the duties and responsibilities that may be given to any Medical Director. The duties and responsibilities outlined in this position may be added to or changed when deemed appropriate and necessary by the person who is supervisorily or managerially responsible for this position.

C: Economic Feasibility (1) (d)
Documentation of Construction Cost Estimate

Turner

Turner Construction Company
5300 Virginia Way
Brentwood, TN 37027
phone: 615-231-6300
fax: 615-231-6301

January 17, 2016

Methodist University Hospital
Attn: Mr. Richard Kelley
1265 Union Ave
Memphis, TN 38104

RE: ***MUH Campus Master Plan - Estimate***
Methodist University Hospital

To Whom It May Concern:

We have prepared a current cost estimate on the Methodist University Hospital located in Memphis, TN. We have reviewed the program and believe that this representation of the scope for this project based on current market conditions, historical data, and schematic architect's documents at this stage will be sufficient for this project. Turner Construction as the Nation's largest Healthcare builder has completed hundreds of projects similar in scope. We have used this historic cost database as a basic of our estimate. Some Tennessee projects that we have used for comparison are the Cookeville Regional Medical Center new patient tower and Vanderbilt Children's Hospital expansion schedule to start this year. We have also looked at 5 other project that are similar in size and scope that we have completed in the last 5 years across the United States. We have included escalation based on our experience and what the market is forecasting until this project begins. The following is our estimated cost:

Sitework - $4,850,000
Building Demolition – $1,900,000
Building Construction - $172,150,000

The above includes 3% escalation until the project begins construction.

Working with HKS Inc., this facility will be designed in accordance with all applicable codes, regulations and guidelines required and in accordance with the equipment manufacturer's specifications at the proposed location of the PET, iMRI and Linear Accelerator units on the Methodist University Hospital campus.

Should you have any questions or need any clarifications regarding this information above, please feel free to contact me.

Sincerely,

Andy Davis
Project Executive
Turner Construction

CC: Chuck Lane (MUH), Marty Keith (MUH), Dave Rosenbaum (MLH), Tom Briggs (HKS)

C: Economic Feasibility
Project Cost Charts

Equipment >$50,000	Qty	Unit Cost	Equipment Cost
iMRI systems	1	3,959,767	3,959,767
Linear Accelerator	1	2,636,000	2,636,000
Optimize Hybrid OR Imaging	1	1,972,443	1,972,443
Skytron Surgical Lighting System	1	135,910	135,910
Maclab Hybrid OR	1	229,494	229,494
Hyrbid Suite	1	230,000	230,000
Injector	1	25,000	25,000
Navigation System Allocation	1	500,000	500,000
Chemistry Analyzer	2	500,000	1,000,000
Hemotology Analyzers	2	500,000	1,000,000
Automated DNA Extractor	2	500,000	1,000,000
PCR Equipment Allocation	2	500,000	1,000,000
Blood Irradiator	1	500,000	500,000
R&F Room	2	350,000	700,000
Pharmacy Carousel	3	250,000	750,000
Automated Chemistry Line	1	250,000	250,000
Automated Hemotology Line	1	250,000	250,000
Immunoassay Analyzer	2	250,000	500,000
Serology Analyzer	2	250,000	500,000
Electrophoresis Analyzer	2	250,000	500,000
Cellavision Analyzer	1	250,000	250,000
Coagulation Analyzer	2	250,000	500,000
Flow Cytometer	2	250,000	500,000
iMRI Systems Surgical Instruments	1	150,000	150,000
Anaerobic Chamber	1	150,000	150,000
Urine Analyzer	2	100,000	200,000
Dispensor, Medication	10	80,000	800,000
Centralized RO	1	60,000	60,000
Critical Care Patient Bed	30	55,000	1,650,000
Perfusion Pumps	6	50,000	300,000
OR Integration System Allocation	20	50,000	1,000,000
Video Tower Allocation	15	50,000	750,000
MRI Contrast Injector	2	50,000	100,000
Stress Test Treadmill	1	50,000	50,000
Hot Lab Hood	2	50,000	100,000
Blood Culture Analyzer	8	50,000	400,000
			$ 24,598,614

C: Economic Feasibility (2)
Documentation of Availability of Funding

Methodist Healthcare

February 10, 2016

Melanie Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building
502 Deaderick Street, 9th Floor
Nashville, TN 37243

Dear Ms. Hill:

This is to certify that Methodist Healthcare – Memphis Hospitals has adequate financial resources for the Methodist Healthcare – University Hospital Onsite Replacement and Modernization project. The applicant, Methodist Healthcare–Memphis Hospitals, is a not-for-profit corporation that operates five Shelby County hospitals under a single license. The applicant is a wholly-owned subsidiary of a broader parent organization, Methodist Healthcare, which is a not-for-profit corporation with ownership and operating interests in multiple other healthcare facilities of several types in West Tennessee. Cash is held at the corporate level. Methodist Healthcare has available cash balances to commit to this project. The capital cost of the project is estimated at $280,000,000.

Sincerely,

Chris McLean
Executive Vice President and Chief Financial Officer

C: Economic Feasibility Historical Chart

OTHER REVENUE AND EXPENSES

Other Operating Revenue:

Cafeteria
Drugs
Telephone rental
Vending
Office Rental
Ground Transportation
Fix Wing
Grants
United Way Grants
Misc. Income

Other Expenses:

Benefits
Repairs and Maintenance
Professional Fees
Contract Services
Accounting/Auditing Fees
Legal/Consulting Fee
Advertising
Dues and Subscriptions
Education/ Travel
Utilities
Insurance
Food services
Laundry Services
Print Shop
Telephone
Transcription
Academic Support
Contributions
License/Accredidations Fees
Postage/Freight
Procurement Card Exp

Other Revenue/Expenses:

Capital Campaign Funding
Interest Income
Gain/Loss on Disposal of PPE

Project Data Chart

Other Operating Revenue:

Cafeteria
Drugs
Gift Shop
Telephone
Vending
Shared Svc
Tuition/Student Fees
Office Rentals
Parking
340b Program
HealthSouth
Trauma Fund
Rental Income
Transp (ground & fixed wing)
Gamma Knife
Grants
Other

C: Economic Feasibility Projected Chart

Projected Data Chart- Other Expenses

	Year 1 2019	Year 2 2020
1 340b Program	$ 24,434	$ 24,554
2 Clinical Trials	$ 564	$ 581
3 Drugs	$ 32,500	$ 33,150
4 Gamma Knife	$ 148	$ 148
5 Grants	$ 35	$ 35
6 HealthSouth	$ 649	$ 649
7 Office Rentals	$ 1,082	$ 1,093
8 Rental Income	$ 91	$ 92
9 Tuition/Student Fees	$ 269	$ 274
10 Vending	$ 143	$ 146
11 Other	$ 513	$ 525
Total Other Revenue	**$ 60,428**	**$ 61,247**

Projected Data Chart- Other Expenses

	Year 1 2019	Year 2 2020
1 Professional Fees	$ 19,539	$ 19,796
2 Contract Srvcs and Maint. Contracts	$ 29,431	$ 29,827
3 Support from Other Departments*	$ 69,909	$ 75,678
4 Repairs and Utilities	$ 15,957	$ 16,633
5 Interest Expense	$ 1,723	$ 1,644
6 All Other Dept. not Otherwise Assigned	$ 49,448	$ 47,998
Total Other Expenses	**$ 186,007**	**$ 191,576**

*Corp Allocation + Phys Margin

C: Economic Feasibility (10)
Financial Statements

METHODIST LE BONHEUR HEALTHCARE
BALANCE SHEET
UNAUDITED ($000's)
DECEMBER, 2015

	CURRENT MONTH
ASSETS:	
CURRENT ASSETS:	
CASH & TEMPORARY INVESTMENTS:	
UNRESTRICTED	968,233
RESTRICTED	22,304
TOTAL CASH & TEMPORARY INVESTMENTS	990,537
ACCOUNTS RECEIVABLE:	
PATIENT	825,157
ALLOW FOR DBTFUL ACCTS & CONTR ADJ	608,806
NET PATIENT ACCOUNTS RECEIVABLE	216,351
MEDICARE / MEDICAID PROGRAMS	0
PLEDGE CAMPAIGN	3,161
OTHER	30,487
TOTAL ACCOUNTS RECEIVABLE	249,999
INVENTORIES	30,548
PREPAID EXP & OTHER CURRENT ASSETS	10,808
ASSETS LIMITED TO USE-CURRENT PORTION	650
TOTAL CURRENT ASSETS	1,282,542
ASSETS LIMIT TO USE-LESS CURR PORTION	36,485
PROPERTY PLANT & EQUIPMENT-NET	932,838
UNAMORTIZED DEBT ISSUE COSTS	10,708
SWAPS MARKET VALUE	0
PLEDGE CAMPAIGN-LONG TERM	4,861
OTHER ASSETS	36,279
TOTAL ASSETS	2,303,713
LIABILITIES AND NET ASSETS:	
CURRENT LIABILITIES:	
ACCOUNTS PAYABLE	112,598
ACCRUED PAYROLL & PAYROLL TAXES	30,268
ACCRUED PTO	38,242
ACCRUED SELF INSURANCE COST	15,685
ACCRUED INTEREST	4,452
OTHER ACCRUED EXPENSES	3,618
MEDICARE / MEDICAID PROGRAMS	100

LONG TERM DEBT-CURRENT PORTION	17,046
TOTAL CURRENT LIABILITIES	222,009
LONG TERM DEBT LESS CURRENT PORTION	551,528
ACCRUED PENSION LIABILITY	112,841
HPL LONG TERM RESERVE	11,210
SWAPS MARKET VALUE	68,773
OTHER LONG TERM LIABILITIES	4,247
MINORITY INTEREST	2,190
TOTAL LIABILITIES	972,798
NET ASSETS:	
UNRESTRICTED	1,305,124
TEMPORARILY RESTRICTED	22,150
PERMANENTLY RESTRICTED	3,641
TOTAL NET ASSETS	1,330,915
TOTAL LIABILITIES AND NET ASSETS	2,303,713

METHODIST LE BONHEUR HEALTHCARE
INCOME STATEMENT
UNAUDITED ($000's)
DECEMBER, 2015

Revenues	
Gross patient service revenues	$ 6,349,011
Deductions from revenue	4,628,840
Net patient service revenues	1,720,171
Other Operating Revenue	136,301
Other Non-Operating Revenue	(5,232)
Total revenues	1,851,240
Expenses	
Salaries and benefits	876,744
Supplies and other	737,976
Depreciation and amortization	106,027
Interest	17,185
Other	31,091
Total expenses	1,706,841
Net Income	$ 144,399

KPMG

METHODIST LE BONHEUR HEALTHCARE AND AFFILIATES

Combined Financial Statements

December 31, 2014 and 2013

(With Independent Auditors' Report Thereon)

KPMG LLP
Triad Centre III
Suite 450
6070 Poplar Avenue
Memphis, TN 38119-3901

Independent Auditors' Report

The Board of Directors
Methodist Le Bonheur Healthcare:

We have audited the accompanying combined financial statements of Methodist Le Bonheur Healthcare and Affiliates (the System), which comprise the combined balance sheets as of December 31, 2014 and 2013, and the related combined statements of operations, changes in net assets, and cash flows for the years then ended, and the related notes to the combined financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these combined financial statements in accordance with U.S. generally accepted accounting principles; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of combined financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility

Our responsibility is to express an opinion on these combined financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the combined financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the combined financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the combined financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the combined financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the combined financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

KPMG

Opinion

In our opinion, the combined financial statements referred to above present fairly in all material respects, the financial position of Methodist Le Bonheur Healthcare and Affiliates as of December 31, 2014 and 2013, and the results of their operations and their cash flows for the years then ended in accordance with U.S. generally accepted accounting principles.

KPMG LLP

Memphis, Tennessee
April 30, 2015

METHODIST LE BONHEUR HEALTHCARE AND AFFILIATES

Combined Balance Sheets

December 31, 2014 and 2013

(In thousands)

Assets		2014	2013
Current assets:			
Cash and cash equivalents	$	130,129	35,310
Investments		780,462	778,974
Assets limited as to use – current portion		766	962
Net patient accounts receivable		214,034	210,819
Other current assets		61,693	57,374
Total current assets		1,187,084	1,083,439
Assets limited as to use, less current portion		36,897	39,495
Property and equipment, net		901,383	901,227
Other assets		59,036	60,639
Total assets	$	2,184,400	2,084,800
Liabilities and Net Assets			
Current liabilities:			
Accounts payable	$	53,585	65,912
Accrued expenses and other current liabilities		101,698	93,486
Due to third-party payors		43,629	13,551
Long-term debt – current portion		15,464	15,637
Total current liabilities		214,376	188,586
Long-term debt, less current portion		568,599	584,454
Estimated professional and general liability costs		18,511	17,304
Accrued pension cost		118,512	49,328
Other long-term liabilities		73,927	55,694
Total liabilities		993,925	895,366
Net assets:			
Unrestricted		1,159,676	1,158,133
Temporarily restricted		24,597	23,103
Permanently restricted		3,704	3,504
Total net assets attributable to Methodist Le Bonheur Healthcare		1,187,977	1,184,740
Noncontrolling interests		2,498	4,694
Total net assets		1,190,475	1,189,434
Commitments and contingencies			
Total liabilities and net assets	$	2,184,400	2,084,800

See accompanying notes to combined financial statements.

METHODIST LE BONHEUR HEALTHCARE AND AFFILIATES

Combined Statements of Operations

Years ended December 31, 2014 and 2013

(In thousands)

	2014	2013
Unrestricted revenues and other support:		
Net patient service revenue	$ 1,721,566	1,653,966
Provision for uncollectible accounts	(155,629)	(154,171)
Net patient service revenue less provision for uncollectible accounts	1,565,937	1,499,795
Other revenue	87,499	69,719
Net assets released from restrictions used for operations	12,154	12,781
Total unrestricted revenues and other support	1,665,590	1,582,295
Expenses:		
Salaries and benefits	817,920	773,377
Supplies and other	661,492	634,842
Depreciation and amortization	102,826	89,108
Interest	26,798	25,874
Total expenses	1,609,036	1,523,201
Operating income	56,554	59,094
Nonoperating gains (losses):		
Investment income, net	36,555	40,979
Change in fair value of interest rate swaps	(20,524)	33,256
Unrealized gain on trading securities, net	5,653	39,536
Impairment of land	(882)	—
Total nonoperating gains, net	20,802	113,771
Revenues, gains and other support in excess of expenses and losses, before noncontrolling interests	77,356	172,865
Noncontrolling interests	(1,548)	(1,646)
Revenues, gains and other support in excess of expenses and losses	75,808	171,219
Other changes in unrestricted net assets:		
Accrued pension cost adjustments	(75,385)	133,080
Other	—	42
Net assets released from restrictions used for capital purposes	1,120	1,653
Increase in unrestricted net assets	$ 1,543	305,994

See accompanying notes to combined financial statements.

METHODIST LE BONHEUR HEALTHCARE AND AFFILIATES

Combined Statements of Changes in Net Assets

Years ended December 31, 2014 and 2013

(In thousands)

	Unrestricted	Temporarily restricted	Permanently restricted	Noncontrolling interests	Total
Balances at December 31, 2012	$ 852,139	20,282	3,351	4,722	880,494
Revenues, gains and other support in excess of expenses and losses	171,219	—	—	1,646	172,865
Distributions to minority shareholders	—	—	—	(1,674)	(1,674)
Accrued pension cost adjustments	133,080	—	—	—	133,080
Other	42	—	—	—	42
Donor-restricted gifts, grants, and bequests	—	16,432	153	—	16,585
Investment income, net	—	823	—	—	823
Net assets released from restrictions used for operations	—	(12,781)	—	—	(12,781)
Net assets released from restrictions used for capital purposes	1,653	(1,653)	—	—	—
Change in net assets	305,994	2,821	153	(28)	308,940
Balances at December 31, 2013	1,158,133	23,103	3,504	4,694	1,189,434
Revenues, gains and other support in excess of expenses and losses	75,808	—	—	1,548	77,356
Distributions to minority shareholders	—	—	—	(3,744)	(3,744)
Accrued pension cost adjustments	(75,385)	—	—	—	(75,385)
Donor-restricted gifts, grants, and bequests	—	14,138	200	—	14,338
Investment income, net	—	630	—	—	630
Net assets released from restrictions used for operations	—	(12,154)	—	—	(12,154)
Net assets released from restrictions used for capital purposes	1,120	(1,120)	—	—	—
Change in net assets	1,543	1,494	200	(2,196)	1,041
Balances at December 31, 2014	$ 1,159,676	24,597	3,704	2,498	1,190,475

See accompanying notes to combined financial statements.

METHODIST LE BONHEUR HEALTHCARE AND AFFILIATES

Combined Statements of Cash Flows

Years ended December 31, 2014 and 2013

(In thousands)

	2014	2013
Cash flows from operating activities:		
Change in net assets	$ 1,041	308,940
Adjustments to reconcile change in net assets to net cash provided by operating activities, net of effects of acquisitions:		
Depreciation and amortization	102,826	89,108
Unrealized and realized gains on trading securities, net	(17,856)	(56,177)
Change in fair value of interest rate swaps	20,524	(33,256)
Provision for uncollectible accounts	155,629	154,171
Restricted contributions and investment income	(993)	(1,142)
Equity in net income (loss) of equity investees	4,238	(1,668)
Impairment of land	882	—
Gain on disposal of property and equipment	(127)	45
Accrued pension cost adjustments	75,385	(133,080)
Changes in operating assets and liabilities:		
Accounts receivable	(158,844)	(174,888)
Other current assets	(4,195)	(7,708)
Other assets	(4,085)	(5,091)
Accounts payable, accrued expenses and due to third-party payors	30,559	6,114
Other long-term liabilities, estimated professional and general liability costs and accrued pension costs	(7,285)	(22,770)
Net cash provided by operating activities	197,699	122,598
Cash flows from investing activities:		
Capital expenditures	(108,093)	(166,824)
Proceeds from sales of property and equipment	967	245
Sales of investments and assets limited as to use	1,283,430	1,422,011
Purchases of investments and assets limited as to use	(1,264,268)	(1,397,359)
Purchase of businesses	(624)	(2,521)
Net cash used in investing activities	(88,588)	(144,448)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt	423	—
Repayment of long-term debt	(15,708)	(15,659)
Restricted contributions and investment income	993	1,142
Net cash used in financing activities	(14,292)	(14,517)
Net increase (decrease) in cash and cash equivalents	94,819	(36,367)
Cash and cash equivalents at beginning of year	35,310	71,677
Cash and cash equivalents at end of year	$ 130,129	35,310

See accompanying notes to combined financial statements.

C: Orderly Development (1)
List of Managed Care Contracts

SCHEDULE N - HEALTH CARE PLANS ACCEPTED* State ID 79276

The Health Consumer Right-to-Know Act of 1998 which was signed by Governor Sunquist in May, 1998 requires hospitals to report to the Department of Health "health care plans accepted by the hospital" as well as a variety of information that is included in earlier schedules of the Joint Annual Report. In order to allow the Joint Annual Report to meet the entire reporting requirement described in this act, please list all health insurance plans with which you currently - as of the last day of this reporting period - have a valid contract. List each plan separately not just the name of the company. For example, if you have contracts to provide services to individuals enrolled in Blue Choice and Blue Preferred, list both plans and do not only list Blue Cross & Blue Shield of Tennessee.

Plans:

Ace Pump
American Healthcare Alliance
AR BCBS Exchange
AR BCBS First Source
AR BCBS True Blue PPO
AR BCBS Health Advantage HMO
AR BCBS Medi-Pak (Medicare Advantage)
Arkansas Higher Education Consortium
Arkansas Managed Care Organization
Arkansas State Police
Assurant Health
BCBSTN BlueCare/TennCare Select
BCBSTN Medicare Advantage
BCBSTN Network E - Exchange
BCBSTN Network P
BCBSTN Network S
Cigna HMO
Cigna PPO
Cigna Managed Care (Flex)
Cigna Exclusive PPO
Cigna Exchange
City of Dyersburg
CorVel Corporation - Work Comp
HealthSCOPE Benefits Inc
HealthSpring (Medicare Advantage HMO)
Magnolia Health Plan - MS CAN
Methodist LeBonheur Health Care
Municipal Health Benefit Fund
North Mississippi Health Link Inc
North Mississippi Health Service Employee Health Plan
NovaNet Inc
NovaNet Work Comp
Prime Health Services Inc - Work Comp
Razorback Concrete
SHARP PHO
United Healthcare
United Healthcare Americhoice (TennCare)
United Healthcare Secure Horizons (Medicare Advantage)
United Healthcare SNP

C: Orderly Development (6)
List of Clinical Affiliations

Methodist Healthcare
Clinical Affiliation Agreements

Arkansas Northeastern College	Clinical Affiliation Agreement / Nursing Admin
Arkansas State University	Clinical Affiliation Agreement / Nursing Education
Arkansas State University	Clinical Affiliation Agreement / Laboratory
Arkansas State University	Clinical Affiliation Agreement / Allied Health/Physical Therapy
Auburn University	Clinical Affiliation Agreement / Nursing Admin
Baptist College of Health Sciences	Clinical Affiliation Agreement / Radiation Therapy
Baptist College of Health Sciences	Clinical Affiliation Agreement / Nursing Education
Baylor University	Clinical Affiliation Agreement / Speech Pathology
Bellarmine University	Clinical Affiliation Agreement / Physical Therapy
Belmont University	Clinical Affiliation Agreement / Physical Therapy
Bethel College	Clinical Affiliation Agreement / Education
Christian Brothers University	Clinical Affiliation Agreement / LEAD
College of Health Professions	Clinical Affiliation Agreement / Nursing Admin
Concorde Career College	Clinical Affiliation Agreement / Administration
Concorde Career Institute	Clinical Affiliation Agreement / Pharmacy
Concorde Career Institute	Clinical Affiliation Agreement / Nursing Education
Concorde Career Institute	Clinical Affiliation Agreement / Respiratory Care
Creighton University	Clinical Affiliation Agreement / Physical Therapy
Crichton College Memphis	Clinical Affiliation Agreement / Nursing Admin
Deaconess College of Nursing, I.P.	Clinical Affiliation Agreement / Nursing Education
Delta State University	Clinical Affiliation Agreement / Nursing Admin
East Arkansas Community College	Clinical Affiliation Agreement / Nursing Admin
East Tennessee State University	Clinical Affiliation Agreement / Physical Therapy
Elon College	Clinical Affiliation Agreement / Physical Therapy
High-Tech Institute-Memphis	Clinical Affiliation Agreement / Surgery / OR
Itawamba Community College	Clinical Affiliation Agreement / Physical Therapy
James Madison University	Clinical Affiliation Agreement / Rehabilitation Services
Loma Linda University	Clinical Affiliation Agreement / Physical Therapy
Louisiana State University Health Sciences Center -School of Allied Health Professions	Clinical Affiliation Agreement / Education
LSU Health Sciences Center	Clinical Affiliation Agreement / Administration
Medical University of South Carolina	Clinical Affiliation Agreement / Rehabilitation Services
Mississippi University For Women	Clinical Affiliation Agreement / Nursing Admin
Remington College Memphis	Clinical Affiliation Agreement / Education
Northeast Louisiana University	Clinical Affiliation Agreement / Physical Therapy
Northwest Mississippi Community College	Clinical Affiliation Agreement / Nursing Admin
Northwest Mississippi Community College	Clinical Affiliation Agreement / Emergency Department Admin
Northwest Mississippi Community College	Clinical Affiliation Agreement / Respiratory Care
Ozarka Technical College	Clinical Affiliation Agreement / Physical Therapy
Radiographics	Clinical Affiliation Agreement / Rehabilitation Services
Rockhurst University	Clinical Affiliation Agreement / Rehabilitation Services
Saint Louis University, Dept of Physical Therapy	Clinical Affiliation Agreement / Physical Therapy
Southwest Baptist University	Clinical Affiliation Agreement / Physical Therapy
Southwest Tennessee Community College	Clinical Affiliation Agreement / Laboratory
Southwest Tennessee Community College	Clinical Affiliation Agreement / Emergency Department
State of Colorado, Department of Higher Education-state Board For Community Colleges and Occupational Education	Clinical Affiliation Agreement / Physical Therapy
Tennessee State University	Clinical Affiliation Agreement / Physical Therapy
Tennessee Technology Center At Covington, Munford Campus	Clinical Affiliation Agreement / Nursing Admin
Tennessee Technology Center at Memphis	Clinical Affiliation Agreement / Education
Tennessee Technology Center at Memphis	Clinical Affiliation Agreement / Surgery / OR
Tennessee Technology Center at Memphis	Clinical Affiliation Agreement / Nursing Education
The University of Tennessee	Clinical Affiliation Agreement / Nursing Education
Union University	Clinical Affiliation Agreement / Nursing Admin
University of Findlay	Clinical Affiliation Agreement / Physical Therapy
University of Memphis	Clinical Affiliation Agreement / Nursing Education
University of Memphis	Clinical Affiliation Agreement / Education

Methodist Healthcare
Clinical Affiliation Agreements

University of Memphis	Clinical Affiliation Agreement / Physical Therapy
University of Memphis	Clinical Affiliation Agreement / Audiology
University of Mississippi	Clinical Affiliation Agreement / Pharmacy
University of Mississippi	Clinical Affiliation Agreement / Speech Pathology
University of Mississippi Medical Center	Clinical Affiliation Agreement / Physical Therapy
University of New Hampshire	Clinical Affiliation Agreement / Laboratory
University of North Florida	Clinical Affiliation Agreement / Physical Therapy
University of South Alabama School of Nursing	Clinical Affiliation Agreement / Nursing Admin & Education
University of Southern Mississippi	Clinical Affiliation Agreement / Speech Pathology
University of St. Augustine for Health Science Institute of Occupational Therapy Institute of Physical Therapy	Clinical Affiliation Agreement / Physical Therapy
University of Tennessee	Clinical Affiliation Agreement / Corporate Affairs
University of Tennessee	Clinical Affiliation Agreement / Nursing Admin
University of Tennessee	Clinical Affiliation Agreement / Pharmacy
University of Tennessee	Clinical Affiliation Agreement / Physical Therapy
University of Tennessee	Clinical Affiliation Agreement / Pathology
University of Tennessee at Chattanooga	Clinical Affiliation Agreement / LEAD
University of Tennessee at Chattanooga	Clinical Affiliation Agreement / Physical Therapy
University of Tennessee Health Science Center	Clinical Affiliation Agreement / Occupational Therapy
University of Tennessee Health Science Center	Clinical Affiliation Agreement / Nursing Education
UT Medical Group, Inc	Clinical Affiliation Agreement / Surgery / OR
Vanderbilt University	Clinical Affiliation Agreement / Nursing Admin
Vanderbilt University	Clinical Affiliation Agreement / Speech Pathology
Washington University School of Medicine	Clinical Affiliation Agreement / Physical Therapy
Xavier University	Clinical Affiliation Agreement / Physical Therapy

C: Orderly Development (7) (C)
License from Board of Licensing Health Care Facilites

Board for Licensing Health Care Facilities

State of Tennessee

0000000109

No. of Beds 1583

DEPARTMENT OF HEALTH

This is to certify, that a license is hereby granted by the State Department of Health to

METHODIST HEALTHCARE - MEMPHISHOSPITALS *to conduct and maintain a*

Hospital METHODIST HEALTHCARE - MEMPHIS HOSPITALS

Located at 1265 UNION AVENUE, MEMPHIS

County of SHELBY *, Tennessee.*

This license shall expire SEPTEMBER 14 *,* 2016 *, and is subject to the provisions of Chapter 11, Tennessee Code Annotated. This license shall not be assignable or transferable, and shall be subject to revocation at any time by the State Department of Health, for failure to comply with the laws of the State of Tennessee or the rules and regulations of the State Department of Health issued thereunder.*

In Witness Whereof, we have hereunto set our hand and seal of the State this 23RD *day of* JULY *,* 2015 *.*

In the Distinct Category(ies) of: GENERAL HOSPITAL
PEDIATRIC PRIMARY HOSPITAL

By Vincent J. Davis, MPH
DIRECTOR, DIVISION OF HEALTH CARE FACILITIES

By
COMMISSIONER

182

:P011

C: Orderly Development (7) (d) (1)
TDH Licensure Survey and Plan of Correction

FEB 22 20

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
WEST TENNESSEE HEALTH CARE FACILITIES
781-B AIRWAYS BOULEVARD
JACKSON, TENNESSEE 38301-3203

February 13, 2008

Ms. Peggy Troy, Administrator
Memphis Healthcare Memphis Hospitals
1211 Union Avenue, Ste 700
Memphis, TN 38104

RE: Licensure Surveys

Dear Ms. Troy:

On **January 17, 2008,** licensure surveys were completed at your facility. Your plans of correction for these surveys have been received and were found to be acceptable.

Thank you for the consideration shown during this survey.

Sincerely,

Celia S Kelley/TW

Celia Skelley, MSN, RN
Public Health Nurse Consultant 2

CES/TJW

FEB - 4 2008

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
WEST TENNESSEE HEALTH CARE FACILITIES
781-B AIRWAYS BOULEVARD
JACKSON, TENNESSEE 38301-3203

January 29, 2008

Ms. Peggy Troy, Administrator
Methodist Healthcare Memphis Hospitals
1211 Union Avenue, Ste 700
Memphis, TN 38104

RE: Licensure Surveys

Dear Ms. Troy:

Enclosed is the statement of deficiencies for the licensure surveys completed at your facility on **January 17, 2008**. Based upon 1200-8-1, you are asked to submit an acceptable plan of correction for achieving compliance with completion dates and signature within **ten (10) days from the date of this letter**.

Please address each deficiency separately with positive and specific statements advising this office of a plan of correction that includes acceptable time schedule, which will lead to the correction of the cited deficiencies. **Enter on the right side of the State Form, opposite the deficiencies,** your planned action to correct the deficiencies and the expected completion date. The completion date can be no longer than **45 days from the day of survey**. Before the plan can be considered "acceptable," it must be signed and dated by the administrator.

Your plan of correction must contain the following:

- How the deficiency will be corrected;
- How the facility will prevent the same deficiency from recurring.
- The date the deficiency will be corrected;
- How ongoing compliance will be monitored.

Please be advised that under the disclosure of survey information provisions, the Statement of Deficiencies will be available to the public.

If assistance is needed, please feel free to call me at 731-421-5113.

Sincerely,

Celia Skelley, MSN, RN
Public Health Consultant Nurse 2

CS/TW

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	TN#531109	A. BUILDING 03 - METHODIST NORTH BUIL B. WING	01/16/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
METHODIST HEALTHCARE MEMPHIS HOSPIT	1265 UNION AVE SUITE 700 MEMPHIS, TN 38104

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
H 871	1200-8-1-.08 (1) Building Standards. (1) The hospital must be constructed, arranged, and maintained to ensure the safety of the patient. This Rule is not met as evidenced by: Methodist North Based on observation, it was determined that the facility failed to maintain all parts of the building. The findings included; On 1/16/08 these items were found during the tour of the building: a. On the 5th floor a sprinkler head defector was found bent by room 511 in the corridor b. On the 4th floor the oxygen storage room door would not close and latch. c. On the 3rd floor a penetration was found around the duct above the ceiling by room 308. d. On the 2nd floor at the entrance of the Cath lab by the elevators the hand rail had came lose from the wall. e. On the 2nd floor the fire doors(2-FD-222) at the entrance of the Cath Lab did not close and latch. f. On the 2nd floor at the Cardiac Short Stay a hole in the wall was found behind the fire door. g. On the 1st floor in the O R Preop holding, storage was being stored in the patient holding areas. h. In the Newborn Instension Care has 2 of 3 Emergency lights that did not work when tested. i. The door to the oxygen storage room (140) did not close and latch. j. The smoke detector outside the Dialysis room is approximately 12 inches from the supply vent from the air conditioner.	H 871	Building Standards a. Sprinkler head was repaired. A full inspection of corridor sprinkler heads was completed on 02/06/2008 with findings of 7 bent heads from a total of 278 inspected. These sprinkler heads will be replaced by March 7th. b. Door latch was replaced. Random fire door inspections will continue to ensure that all fire doors are included in the program and not just those that are located in the hallways at fire barriers. c. Repaired penetration. We believe this to be an isolated occurrence as no other penetrations were found. Continue quarterly random penetration inspections and annual full building penetration inspections. d. Changed hand rail to wall guard. Will inspect elevator service lobbies for best application of wall guard versus hand rails and change as appropriate. e. Door latch was repaired on Continue random fire door inspections and ensure that all fire doors are included in the program. f. The hole in the wall has been repaired. This appeared to an isolated incident, which occurred very recently. An inspection of every set of fire doors that are held open found that this was the only door with an issue.	01/23/08 01/17/08 01/16/08 01/22/08 01/17/08 01/18/08

Division of Health Care Facilities

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

STATE FORM 6899 VQ4921 If continuation sheet 1 of 2

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	TN#531109	A. BUILDING 03 - METHODIST NORTH BUIL B. WING	01/16/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
METHODIST HEALTHCARE MEMPHIS HOSPIT	1265 UNION AVE SUITE 700 MEMPHIS, TN 38104

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
H 871	Continued From page 1 k. In the basement 3 tables, a screen and a small metal cart are sitting in the corridor of the medical records Methodist South, No Deficiencies Methodist University Hospital, No Deficiencies Methodist Germantown Hospital, No Deficiencies Methodist Behavioral Health Hospital, No Deficiencies Methodist Lebonheur Childrens Hospital, No Deficiencies	H 871	Continued from page 1 g. Supplies were immediately removed during the survey. Unannounced random inspections will be conducted and documented by Safety / Facilities Services at least monthly in this area to ensure compliance for the next 3 months. Any deficiencies will be immediately corrected and in-service training will be immediately provided to department personnel. h. Emergency lights were replaced. Testing of the battery powered lights will occur on a monthly basis. i. Door latch was replaced. Continue random fire door inspections and ensure that all fire doors are included in the program and not just those that are located in the hallways at fire barriers. j. Smoke detector was immediately moved on the day of the inspection. As we find smoke detectors within 3 feet of a supply / return diffusers, we will move them. We aware of this requirement for all new construction / renovations and will enforce compliance. k. All items were immediately removed from the corridor during the inspection. Unannounced random inspections will be conducted and documented by Safety / Facilities Services at least monthly in this area to ensure compliance for the next 3 months. Any deficiencies will be immediately corrected and in-service training will be immediately provided to department personnel.	01/16/08 01/21/08 01/17/2008 01/16/08 01/16/08

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	TN#531109	A. BUILDING _____ B. WING _____	01/17/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
METHODIST HEALTHCARE MEMPHIS HOSPIT	1265 UNION AVE SUITE 700 MEMPHIS, TN 38104

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
H 732	1200-8-1-.06 (9)(b) Basic Hospital Functions (9) Food and Dietetic Services. (b) The hospital must designate a person to serve as the food and dietetic services director with responsibility for the daily management of the dietary services. The food and dietetic services director shall be: 1. A dietitian; or 2. A graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association; or 3. A graduate of a state-approved course that provided ninety (90) or more hours of classroom instruction in food service supervision and has experience as a food service supervisor in a health care institution with consultation from a qualified dietitian. This Rule is not met as evidenced by: Based on review of the hospital's food service contract,of licensure regulations, of personnel files and interviews it was determined the facility failed to meet licensure qualification requirements for 3 of 5 facility Food Service Directors (Facility # 1, 2, and 3) under the hospital license and to follow these State Hospital Regulations. The findings included: 1. Review of the hospital contract for dietary services revealed the following documentation under Article 4 - Compliance with laws: "4.1 Compliance. [The food service contract	H 732	Basic Hospital Functions Qualified Interim Food and Nutrition Services Director has been named for Methodist Le Bonheur Children's Medical Center, Methodist North Hospital and Methodist South Hospital. The Food and Nutrition Services Director job description has been revised to require one of the following: 1) a dietician; or 2) a graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association; or 3) a graduate of a state-approved course that provided ninety (90) or more hours of classroom instruction in food service supervision and has experience as a food service supervisor in a health care institution with consultation from a qualified dietitian. Food and Nutrition Services Director positions have been posted and recruitment will continue to permanently fill the positions.	02/29/08

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	TN#531108	A. BUILDING _____ B. WING _____	01/17/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
METHODIST HEALTHCARE MEMPHIS HOSPIT	1255 UNION AVE SUITE 700 MEMPHIS, TN 38104

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
H 732	Continued From page 1 company] and the System agree to comply with all applicable laws, rules and regulations". 2. Review of personnel files for the Food Services Directors at Facilities 1, 2 and 3, failed to show they met the licensure regulations for a food service director. During an interview on 1/14/08, at 10:30 AM, the Food Service Director for Facility #1 confirmed he/she did not have the qualifications to meet the licensure regulation. During an interview on 1/15/08, at 9:30 AM, the Food Service Director for Facility #2 confirmed he/she did not have the qualifications to meet the licensure regulation. During an interview on 1/16/08, at 1:30 PM, the Hospital Clinical Risk Management Director was unable to provide documentation that the Food Service Directors from Facility 1, 2 or 3 met these Licensure Regulations.	H 732	Continued from page 1 A check off sheet will be utilized to ensure that before an individual is offered a position as Food and Nutrition Director at any facility in Methodist Le Bonheur Healthcare, the above qualifications are met and one of the following is provided to the HR Recruiter and/or Regional Director of Operations: 1) Copy of CDR Registered Dietitian card, or 2) Copy of CDR Registered Dietetic Technician card, or 3) Copy of certificate of graduation from a state approved CDM class. There will be three (3) required levels of approval for each candidate that is chosen for the food and dietetic services director position at Methodist Le Bonheur Healthcare: 1) Regional Director of Operations with Morrison 2) Regional Vice President with Morrison 3) Methodist Le Bonheur Healthcare Facility Administrative Liaison or the Methodist Le Bonheur Healthcare Facility Human Resource Director. The dietary department will be included in the quarterly Human Resource Department audit. The facility liaison Director at each facility will review the personnel files on an annual basis and at time of new hire.	

C: Orderly Development (7) (d) (2)
JCAHO Accreditation and Survey Summary

Methodist Healthcare Memphis Hospitals

Memphis, TN

has been Accredited by

The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

Hospital Accreditation Program

April 20, 2013

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin, MD.
Chair, Board of Commissioners

Organization ID #: 7874
Print/Reprint Date: 06/19/13

Mark R. Chassin, MD, FACP, MPP, MPH
President

The Joint Commission is an independent, not-for-profit, national body that oversees the safety and quality of health care and other services provided in accredited organizations. Information about accredited organizations may be provided directly to The Joint Commission at 1-800-994-6610. Information regarding accreditation and the accreditation performance of individual organizations can be obtained through The Joint Commission's web site at www.jointcommission.org.

This reproduction of the original accreditation certificate has been issued for use in regulatory/payer agency verification of accreditation by The Joint Commission. Please consult Quality Check on The Joint Commission's website to confirm the organization's current accreditation status and for a listing of the organization's locations of care.

The Joint Commission

June 11, 2013

Re: # 7874
CCN: #440049
Program: Hospital
Accreditation Expiration Date: April 20, 2016

Gary S. Shorb
President/CEO
Methodist Healthcare Memphis Hospitals
1211 Union Avenue
Memphis, Tennessee 38104

Dear Mr. Shorb:

This letter confirms that your April 15, 2013 - April 19, 2013 unannounced full resurvey was conducted for the purposes of assessing compliance with the Medicare conditions for hospitals through The Joint Commission's deemed status survey process.

Based upon the submission of your evidence of standards compliance on June 03, 2013 and June 04, 2013, the areas of deficiency listed below have been removed. The Joint Commission is granting your organization an accreditation decision of Accredited with an effective date of April 20, 2013. We congratulate you on your effective resolution of these deficiencies.

§482.11 Compliance with Federal, State and Local Laws
§482.13 Patient's Rights
§482.25 Pharmaceutical Services
§482.41 Physical Environment
§482.51 Surgical Services

The Joint Commission is also recommending your organization for continued Medicare certification effective April 20, 2013. Please note that the Centers for Medicare and Medicaid Services (CMS) Regional Office (RO) makes the final determination regarding your Medicare participation and the effective date of participation in accordance with the regulations at 42 CFR 489.13. Your organization is encouraged to share a copy of this Medicare recommendation letter with your State Survey Agency.

This recommendation applies to the following location(s):

Breast Diagnostic Center - Germantown
7945 Wolf River Blvd., Germantown, TN, 38138

Cardiovascular Outpatient Diagnostic Center
7460 Wolf River Blvd., Germantown, TN, 38138

Le Bonheur Children's Hospital
848 Adams, Memphis, TN, 38103

Le Bonheur Children's Hospital Audiology
7945 Wolf River Blvd., Germantown, TN, 38138

Le Bonheur Cordova Urgent Care
8035 Club Parkway, Cordova, TN, 38018

Le Bonheur East Diagnostic Center
806 Estate Place, Memphis, TN, 38120

Le Bonheur Urgent Care at Hacks Cross
8071 Winchester Rd., Ste. 2, Memphis, TN, 38125

Le Bonheur Urgent Care East
806 Estate Place, Memphis, TN, 38120

Methodist Comprehensive Wound Healing Center
1251 Wesley Drive, Suite 107, Memphis, TN, 38116

Methodist Diagnostic Center Germantown
1377 South Germantown Rd., Germantown, TN, 38138

Methodist Germantown Radiation Oncology Center
1381 South Germantown Rd., Germantown, TN, 38138

Methodist Healthcare Outpatient Services
100 North Humphreys Blvd., Memphis, TN, 38120

Methodist Healthcare Outpatient Services
1588 Union, Memphis, TN, 38104

Methodist Healthcare Outpatient Services
240 Grandview Drive, Brighton, TN, 38011

Methodist Le Bonheur Germantown Hospital
7691 Poplar Avenue, Germantown, TN, 38138

Methodist North Hospital
3960 New Covington Pike, Memphis, TN, 38128

Methodist Sleep Disorders Center
5050 Poplar Suite 300, Memphis, TN, 38114

The Joint Commission

Methodist South Hospital
1300 Wesley Drive, Memphis, TN, 38116

Methodist University Hospital
1265 Union Avenue, Memphis, TN, 38104

MHMH GI Lab - Southwind
3725 Champion Hills Drive, Memphis, TN, 38125

Midtown Diagnostic Center
1801 Union Ave, Memphis, TN, 38104

North Comprehensive Wound Healing Center
3950 New Covington Pike, Memphis, TN, 38128

We direct your attention to some important Joint Commission policies. First, your Medicare report is publicly accessible as required by the Joint Commission's agreement with the Centers for Medicare and Medicaid Services. Second, Joint Commission policy requires that you inform us of any changes in the name or ownership of your organization, or health care services you provide.

Sincerely,

Mark Pelletier

Mark G. Pelletier, RN, MS
Chief Operating Officer
Division of Accreditation and Certification Operations

cc: CMS/Central Office/Survey & Certification Group/Division of Acute Care Services
CMS/Regional Office 4 /Survey and Certification Staff

C: Proof of Publication
Proof of Publication

of the sale, or credit bid from a bank or other lending entity pre-approved by the successor trustee. The sale is free

Lot 21, to the point of beginning, containing 0.361 acres or 15,740.12 square feet. Bearing are magnetic, taken September 3, 1996, James W. Crocker, TN RLS 1125, P.O. Box 923, Martin, TN 38237. Being the same property conveyed to Ryan S. Connor in Warranty Deed, as filed at Book D416, Page 392 in the Register's Office of Weakley County.

ALSO KNOWN AS: 200 Meadow Brook, Martin, TN 38237

This sale is subject to all matters shown on any applicable recorded plat; any unpaid taxes; any restrictive covenants, easements, or setback lines that may be applicable; any statutory rights of redemption of any governmental agency, state or federal; any prior liens or encumbrances as well as any priority created by a fixture filing; and to any matter that an accurate survey of the premises might disclose. In addition, the following parties may claim an interest in the above-referenced property:

RYAN S. CONNOR
MIDLAND FUNDING, LLC

The sale held pursuant to this Notice may be rescinded at the Successor Trustee's option at any time. The right is reserved to adjourn the day of the sale to another day, time, and place certain without further publication, upon announcement at the time and place for the sale set forth above. W&A No. 310052

DATED February 2, 2016
WILSON & ASSOCIATES
P.L.L.C.,
Successor-Trustee
1521 Merrill Drive, Suite D-220
Little Rock, Arkansas 72211
(501) 219-9388
W&A No.-310052
CA3T-
2/10/16
2/17/16
2/24/16
FOR SALE INFORMATION, VISIT WWW.MYFIR.COM and WWW.REALTYTRAC.COM

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that: Methodist Healthcare-Memphis Hospitals d/b/a Methodist University Hospital (a general hospital), owned and managed by Methodist Healthcare-Memphis Hospitals (a not for profit corporation), intends to file an application for a Certificate of Need for new construction and renovation of 470,000 SF of space at Methodist University Hospital, located at 1211-1265 Union Avenue, Memphis, TN 38104. The project is the onsite replacement and modernization of the campus including the construction of a new patient tower and adjacent building to consolidate ambulatory services. There is no change to the 617 licensed beds, yet 28 medical-surgical beds will be converted to critical care beds, and 204 beds will be relocated to the new patient tower. The project will add an intraoperative MRI (IMRI), will add a third Linear Accelerator to existing Linear Accelerator services, and will relocate PET,CT and infusion equipment and services from 1588 Union Avenue. The project does not initiate or discontinue any other health service. The estimated project cost is $280,000,000.

The anticipated date of filing the application is on or before February 15, 2016. The contact person for this project is Carol Weidenhoffer, Senior Director of Planning, Research and Development, who may be reached at: Methodist Healthcare, 1407 Union Avenue, Suite 300, Memphis, TN, 38104, 901-516-0679.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street, Nashville, Tennessee 37243

Pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

REQUEST FOR PROPOSAL
STATE OF TENNESSEE
State Building Commission Number: 529/000-06-2015
For
Value Added Reseller (VAR) Contracts

The Tennessee Department of General Services is requesting proposals to award multiple contracts to Value Added Resellers (VAR) to provide integrated lighting control systems, lighting fixture installation services, metering capability and other electrical work for the purpose of accomplishing energy savings projects for general government statewide, not limited to State facilities. Projects may include some or all of the following initiatives: lighting replacement or retrofit, LED lighting control, HVAC control system interface and installation, electrical motor and control upgrade, energy management systems and metering capabilities. The State intends to divide the awarded contracts by the Three Grand Divisions as pursuant to Tenn. Code Ann. Title 4, Chapter 1, Part 2. The VAR must be properly licensed in the State of Tennessee and must hold all necessary, appropriate business and professional license to provide service as required. The full text of the RFP for this project will be available at the STREAM website in *.PDF format requiring the *Acrobat Reader* utility. The RFP can be printed from this address:

http://tn.gov/generalservices/article/request-for-proposals

Proposers may request a copy of the RFP by contacting Nickie Smith, RFP Coordinator, at (615) 532-7475. Proposals are expected to be due in March 2016.

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF Shelby

Jeffrey H. Liebman, being first duly sworn, says that he/she is the applicant named in this application or his/her lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Tennessee Health Services and Development Agency and T.C.A. § 68-11-1601, *et seq.*, and that the responses to questions in this application or any other questions deemed appropriate by the Tennessee Health Services and Development Agency are true and complete.

Jeffrey H. Liebman CHIEF EXECUTIVE OFFICER

Jeffrey H. Liebman
CEO, Methodist University Hospital
SVP, Methodist Healthcare

Signature/Title

Sworn to and subscribed before me this the 10 day of February, 2016, a Notary Public in and for the County of Shelby, State of Tennessee.

NOTARY PUBLIC

My Commission expires 9/30/2017.

DEBRA D SAVAGE
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF SHELBY
MY COMM. EXP. SEPT. 30, 2017

HF-0056
Revised 7/02 - All forms prior to this date are obsolete

State of Tennessee
Health Services and Development Agency
Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

March 1, 2016

Carol Weidenhoffer
1407 Union Avenue Suite 300
Memphis, TN 38104

RE: Certificate of Need Application -- Methodist Healthcare-Memphis Hospitals d/b/a Methodist University Hospital - CN1602-009
Modification of a hospital requiring a capital expenditure greater than $5 million and the addition of major medical equipment. The construction and renovation of approximately 470,000 square feet of space at Methodist University Hospital located at 1211-1265 Union Avenue in Memphis (Shelby County), TN 38104. The project involves the onsite replacement and modernization of the hospital campus including the construction of a new patient tower and an adjacent building to consolidate ambulatory services. The project will not increase or decrease the hospital's existing 617 licensed beds. Of the 617 licensed beds, 204 beds will be relocated to the new patient tower and 28 medical-surgical beds will be converted for use as critical beds. As a part of the project, the hospital will add an interoperative, GE Discovery 3.0 Tesla MRI unit (iMRI), an Elekta Versa Linear Accelerator unit and will relocate existing PET, CT and infusion equipment and services. The estimated project cost is $280,000,000.

Dear Ms. Weidenhoffer:

This is to acknowledge the receipt of supplemental information to your application for a Certificate of Need. Please be advised that your application is now considered to be complete by this office.

Your application is being forwarded to Trent Sansing at the Tennessee Department of Health for Certificate of Need review by the Division of Policy, Planning and Assessment. You may be contacted by Mr. Sansing or someone from his office for additional clarification while the application is under review by the Department. Mr. Sansing's contact information is Trent.Sansing@tn.gov or 615-253-4702.

In accordance with Tennessee Code Annotated, §68-11-1601, et seq., as amended by Public Chapter 780, the 60-day review cycle for this project will begin on March 1, 2016. The first sixty (60) days of the cycle are assigned to the Department of Health, during which time a public hearing may be held on your application. You will be contacted by a representative from this Agency to establish the date, time and place of the hearing should one be requested. At the end of the sixty (60) day period, a written report from the Department of Health or its representative will be forwarded to this office for Agency review within the thirty (30)-day period immediately

following. You will receive a copy of their findings. The Health Services and Development Agency will review your application on May 25, 2016. Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. § 68-11-1607(d):

(1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.

(2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have questions or require additional information, please contact me.

Sincerely,

Melanie M. Hill
Executive Director

cc: Trent Sansing, TDH/Health Statistics, PPA

State of Tennessee
Health Services and Development Agency
Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

MEMORANDUM

TO: Trent Sansing, CON Director
Office of Policy, Planning and Assessment
Division of Health Statistics
Andrew Johnson Tower, 2nd Floor
710 James Robertson Parkway
Nashville, Tennessee 37243

FROM: Melanie M. Hill
Executive Director

DATE: March 1, 2016

RE: Certificate of Need Application
Methodist Healthcare-Memphis Hospitals d/b/a Methodist University Hospital - CN1602-009

Please find enclosed an application for a Certificate of Need for the above-referenced project.

This application has undergone initial review by this office and has been deemed complete. It is being forwarded to your agency for a sixty (60) day review period to begin on March 1, 2016 and end on May 1, 2016.

Should there be any questions regarding this application or the review cycle, please contact this office.

Enclosure

cc: Carol Weidenhoffer

Methodist Healthcare

February 9, 2016

Melanie Hill
Executive Director
State of Tennessee
Health Services and Development Agency
Andrew Jackson Building
502 Deaderick Street, 9th Floor
Nashville, TN 37243

Dear Ms. Hill:

Methodist Healthcare, centered in Shelby County, is one of Tennessee's largest healthcare providers. Methodist Healthcare's principal acute care subsidiary organization is Methodist Healthcare--Memphis Hospitals that owns and operates five Shelby County hospitals. Methodist University Hospital is the tertiary, academic medical center located in the heart of the Memphis medical center. Methodist University is filing a Certificate of Need for the onsite replacement and modernization of the hospital campus.

Enclosed in triplicate is our Letter of Intent for this project. The Publication of Intent for this project will be filed in the Commercial Appeal on February 10, 2016. The anticipated filing date for the application is February 12, 2016. Please let us know if you have any questions or need additional information.

Sincerely,

Carol Weidenhoffer

Carol Weidenhoffer
Senior Director of Planning, Research and Development

LETTER OF INTENT
TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY

The Publication of Intent is to be published in the Commercial Appeal which is a newspaper of general circulation in Shelby County, Tennessee, on or before February 10, 2016 for one day.

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This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that: Methodist Healthcare-Memphis Hospitals d/b/a Methodist University Hospital (a general hospital), owned and managed by Methodist Healthcare-Memphis Hospitals (a not for profit corporation), intends to file an application for a Certificate of Need for new construction and renovation of 470,000 SF of space at Methodist University Hospital, located at 1211-1265 Union Avenue, Memphis, TN 38104. The project is the onsite replacement and modernization of the campus including the construction of a new patient tower and adjacent building to consolidate ambulatory services. There is no change to the 617 licensed beds, yet 28 medical-surgical beds will be converted to critical care beds, and 204 beds will be relocated to the new patient tower. The project will add an intraoperative MRI (iMRI), will add a third Linear Accelerator to existing Linear Accelerator services, and will relocate PET, CT and infusion equipment and services from 1588 Union Avenue. The project does not initiate or discontinue any other health service. The estimated project cost is $280,000,000.

The anticipated date of filing the application is on or before February 15, 2016. The contact person for this project is Carol Weidenhoffer, Senior Director of Planning, Research and Development, who may be reached at: Methodist Healthcare, 1407 Union Avenue, Suite 300, Memphis, TN, 38104, 901-516-0679.

Carol Weidenhoffer (Signature) | 2/9/16 (Date) | Carol.Weidenhoffer@mlh.org (E-mail Address)

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The Letter of Intent must be filed in triplicate and received between the first and the tenth day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

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The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

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Supplemental #1
-Original-

Methodist Healthcare
Memphis Hospitals

CN1602-009

SUPPLEMENTAL #1
February 25, 2016
406 pm

METHODIST HEALTHCARE—MEMPHIS HOSPITALS

SUPPLEMENTAL RESPONSE
CN1602-009

ONSITE REPLACEMENT AND MODERNIZATION OF THE METHODIST UNIVERSITY HOSPITAL CAMPUS

MEMPHIS, SHELBY COUNTY

Filed February 2016

SUPPLEMENTAL #1

February 25, 2016
406 pm

1. **Section A, Item 9 (Bed Complement)**
As noted, the applicant's owner Methodist Healthcare-Memphis Hospitals, owns five primary hospitals in Shelby County that operate under the 1,583 bed combined license of Methodist University Hospital issued by the Tennessee Department of Health.

Please also provide a bed complement table with breakout of beds by service for the 1,583 total combined licensed beds of Methodist University Hospital.

In your response, please complete the table below.

Please see the charts below for the Methodist Healthcare-Memphis Hospital licensed and staffed beds by site and by site by service.

Methodist University Hospital-Main and Satellite Campuses

Hospital	Address	Distance from Main hospital campus	Licensed Beds	Staffed Beds	CON Approved and unimplemented beds
Methodist University	1211-1265 Union Ave Memphis, TN 38104	0	617	472	0
Methodist Germantown	7691 Poplar Ave Germantown, TN 38138	12.9	309	309	0
Methodist North	3960 New Covington Pike Memphis, TN 38128	12.6	246	222	0
Methodist South	1300 Wesley Drive Memphis, TN 38116	8.2	156	143	0
LeBonheur Children's	848 Adams Memphis, TN 38103	1.2	255	250	0
Total		NA	1,583	1,396	0

Methodist University Hospital-Main and Satellite Campuses
Current Licensed and Staffed Beds by Service Type

Licensed / Staffed Beds	Med-Surg Adult	Med-Surg Peds	ICU/CCU (incl peds)	Obstetrics	NICU	Psych	Total
	Licensed Beds / Staffed Beds						
Methodist University	511 / 366	0 / 0	72 / 72	0 / 0	0 / 0	34 / 34	617 / 472
Methodist Germantown	195 / 195	12 / 12	32 / 32	46 / 46	24 / 24	0 / 0	309 / 309
Methodist North	210 / 186	0 / 0	36 / 36	0 / 0	0 / 0	0 / 0	246 / 222
Methodist South	120 / 107	0 / 0	16 / 16	14 / 14	6 / 6	0 / 0	156 / 143
LeBonheur Children's	0 / 0	159 / 156	36 / 34	0 / 0	60 / 60	0 / 0	255 / 250
Total	1036 / 854	171 / 168	192 / 190	60 / 60	90 / 90	34 / 34	1583/1396

2. **Section B, Project Description, Item I (Executive Summary)**
The description of the onsite replacement and modernization project on the campus of Methodist University Hospital is noted.

Please briefly describe the relationship, if any, this project has to other recently CON approved Methodist Healthcare-Memphis Hospitals projects such as Methodist University Hospital, CN1208-041A for the replacement and relocation of the applicant's ED and the West Cancer Center, CN1311-043A for the construction of a comprehensive cancer center to be operated as an outpatient department under the applicant's license.

Methodist Le Bonheur Healthcare's mission is to partner with its medical staffs and collaborate with its patients and families to be the leader in high quality, cost effective healthcare in all sectors of the Greater Memphis-Shelby County service area. Methodist Healthcare has strategically placed and maintained hospitals and ambulatory facilities in all quadrants of Shelby County as part of that mission, to provide multiple entry points to acute care for communities of varied social and economic characteristics. Methodist University Hospital is the system's tertiary academic medical center located in the center of the service area in downtown Memphis. This campus renovation project and the Methodist University ED project (CN1208-041A) are both investments in the downtown academic presence.

The projects are related. The proposed project is the next phase of the master plan for the campus. The new Methodist University ED opened in September 2014, and ED volumes have increased slightly more than original projections. With the increase in volumes, there have also been higher levels of acuity for patients admitted through the ED which has driven the need for more critical care beds. Patient flow from the ED to the critical care units is delayed by the lack of beds. As noted in the application, Methodist University has experienced a growth in number of patients being held in the ED as well as an increase in wait times. Again, patient experience suffers along with the delays and inefficiencies related to lack of capacity.

Methodist University is the core teaching hospital for University of Tennessee Health Science Center. The hospital's academic focus offers highly specialized services for complex diseases, illnesses, and injuries, develops technology, and carries out research to improve lives. The regional and national outreach of the academic programs is shifting the need for more intensive medical capacity and need for a state-of-the-art facility. The proposed project converts medical-surgical beds to critical care beds and addresses other patient flow issues with the relocation and consolidation of services in the new patient tower.

The West Cancer Center project CN1311-043A is also related to the proposed project. The integration of cancer care and the process of multidisciplinary patient care is the most progressive and successive clinical method to fight cancer for patients. The development of the West Cancer Center sites – this project in downtown Memphis and the new comprehensive center that just opened in Germantown - is a continued pursuit by Methodist Le Bonheur Healthcare to allow patients to fight on at home. The need for patients to travel or leave home to access clinical trials, state-of-the-art care medicines, state-of-the-art radiation oncology care, and true multidisciplinary care will be eliminated with the integrated cancer projects

The integrated cancer facilities within the new Methodist University Hospital campus will be complimentary and integrated with the West Cancer Center in east Shelby County in Germantown, Tennessee. Patients,

regardless of geography and or demographics will receive the same oncology care throughout the county and surrounding tristate area. Not just the same care by individual physician providers but the same care by the entire Methodist system. Access will increase for patients all across the service area.

Both sites will have integrated operations and a single patient EMR specialized just for oncology patients. Any new presenting patients will go through an integrated tumor / conference board treatment planning process, and then, if necessary referred to a multidisciplinary clinic where the patients sees multiple providers in one setting to discuss and set the oncology treatment plan. This includes; medical, surgical, radiation, and care support services. The comprehensive delivery of cancer care services improves the cancer journey for the patient and their family.

In your response, please also provide a brief update of the 2 projects and the expected date of project completion.

The Methodist University Hospital ED Replacement and Relocation project (CN1208-041A) was opened September 2014. As noted in the Final Project Report that was filed July 2015, there were final change orders that continued through May 2015. Please see Attachment 2 for the Final Report that was filed.

The West Cancer Center in Germantown, Tennessee (CN1311-043A) celebrated the grand opening of the new comprehensive center on November 17, 2015. The integrated services in the new center were opened for operation in December 2015. There is a final State inspection being scheduled for the last phase of the renovations. If the State can inspect in March or April, then final paper work will wrap up in May and June. The Final Project Report is expected to be filed by July 2016.

3. Section B, Project Description, Item II.A and II.E
Item II.A - The Square Footage Chart is noted. To complement the description and chart pertaining to the proposed patient care units in the New Tower as well as the location of all inpatient beds on the campus, please complete the table below.

SUPPLEMENTAL #1
February 25, 2016
406 pm

Hospital Floor	Current Unit Type	Number of Beds (Licensed /Staffed)	# Rooms Private, Semi-Pvt, Other	Proposed Unit Type	Number of Beds (Licensed /Staffed)	# Rooms Private, Semi-Pvt, Other
Thomas 2	M/S Medicine	24 /21	Private		Relocate	
Thomas 6	M/S Neuro	21 / 0	Private	M/S Neuro	14 / 0 7 relocate (6 ICU & 1 M/S)	Private
Thomas 7	M/S Surgical	22 / 0	Private		Relocate Convert to ICU	
Thomas 8	M/S Respiratory	19 / 0	Private	M/S Respiratory	19 / 0	Private
Thomas 10	M/S Transplant	15 / 15	Private		Relocate	
Thomas 11	M/S Renal	18 / 18	Private		Relocate	
Thomas 13	M/S Medicine	21 / 21	Private		Relocate	
East 2	M/S Surgical	14 / 0	Private	M/S Surgical	14 / 0	Private
East 4	ICU Medicine	8 / 8	Private		Relocate	Private
East 5	M/S	18 / 0	Private	M/S	18 / 0	Private
East 6	M/S Neuro Stroke	20 / 0	Private	M/S Neuro Stroke	20 / 0	Private
East 7	ICU Transplant	8 / 8	Private		Relocate	
East 9	M/S General	20 / 0	Private	M/S General	20 / 0	Private
East 10	M/S Transplant	20 / 16	Private		Relocate	
Crews 2	M/S Cancer	23 / 23	Private		Relocate	
Crews 4	M/S Cancer	10 / 10	Private		Relocate	
Crews 4	M/S Cancer	12 / 12	Private		Relocate	
Crews 8	Psych	34 / 34	Private	Thomas 12 & 13	34	Private
Sherard 2	ICU-CV	16 / 16	Private		Relocate	
Tower 4	ICU Medicine	16 / 16	Private	ICU Medicine	16 / 16	Private
Tower 4	ICU Surgical	8 / 8	Private	ICU Surgical	8 / 8	Private
Tower 4	ICU Neuro	16 / 16	Private	ICU Neuro	16 /16	Private
Tower 5	M/S Cardiac	48 / 48	Private	M/S Cardiac	48 /48	Private
Tower 6	M/S Cardiac/Gen	48 / 46	Private	M/S Cardiac/Gen	48 /46	Private
Tower 7	M/S Cardiac	46 / 46	Private	M/S Cardiac	46 /46	Private
Tower 8	M/S Medicine	48 /46	Private	M/S Medicine	48 /46	Private
Tower 9	M/S Neuro	44 / 44	Private	M/S Neuro	44 /24	Private
New Tower 5	ICU	New			30 /30	Private
New Tower 6	ICU	New			30 /30	Private
New Tower 7	M/S	New			36 /36	Private
New Tower 8	M/S	New			36 /36	Private
New Tower 9	M/S	New			36 /36	Private
New Tower 10	M/S	New			36 /36	Private
Total		617/472			617/ 488	

**HSDA staff was unsure whether or not Security Hold Rooms are included in the project? Please confirm.*

With respect to the design of the patient rooms, what is the AIA recommended patient room size for the hospital and how does it compare to existing room sizes of the hospital?

The AIA recommended patient room size is 325 square feet (sf). The patient rooms on the current Methodist University campus range from 180 sf to 250 sf. The proposed new patient tower will consist of larger rooms between 300-325 sf.

Based on the SF Chart and comments on page 8 regarding areas to be renovated, it appears 10% of the 470,000 total SF construction project involve

renovations to existing areas. Please briefly summarize by identifying the areas to be renovated and overriding rationale for same.

Methodist University proposes to relocate the majority of direct patient care services including nursing units from the oldest buildings on campus – Thomas, East and Sherard – to the new patient tower. The master plan identified the need to vacate this space in the older buildings and retain it for future growth for academic and research functions. As plans are developed, Methodist will submit all requests for CON approval if needed.

There are a few floors in these buildings which will be renovated as part of this project including the space for the relocation of Psych beds to 12 and 13 Thomas (22,000 sf) from Crews – which is slated to be demolished. The Lab will also be relocated to 3 Sherard in renovated space (16,500 sf). Then there is 10,500 sf of space needed for administrative/support functions which are relocating to 10 Thomas.

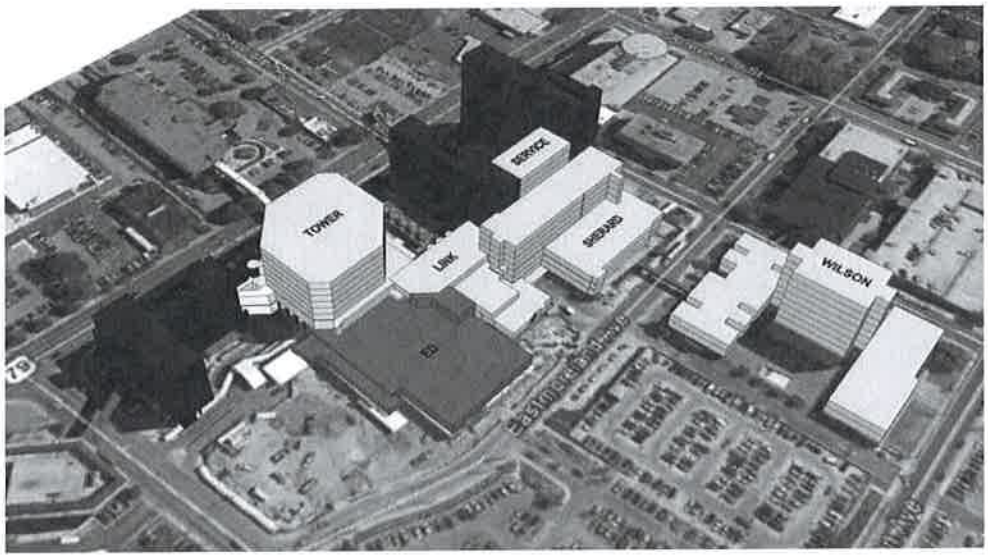
The applicant states on page 8 that the older buildings will be recycled and refurbished for patient education, resident education, support services and administrative functions. In addition to buildings that will be demolished, are there any older buildings that will be vacated and reserved for future plans? Please clarify.

The next response will cover both questions.

If this project were approved and a CON application was subsequently filed for additional beds at a later date, based on the design of the proposed facility, how disruptive would future expansion be to the operations of the facility?

As discussed in the application, Methodist assessed the physical condition of each building on the main campus as part of the master planning process. The assessment included the evaluation of structural, mechanical, and electrical components as well as the age, presence of asbestos and overall functionality. The physical plant alone warrants the need for the project.

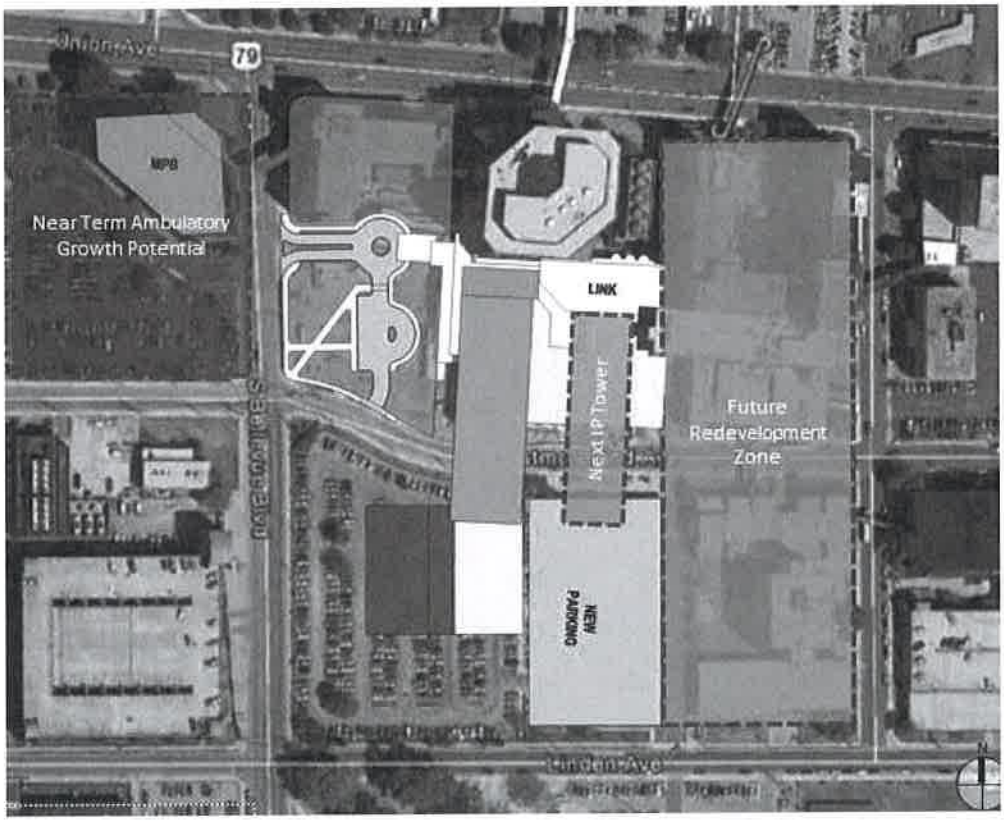
In this view which was included in the application, the assessment of the building conditions shows the two prime corners on Union Avenue are occupied by the lowest ranking buildings, Thomas and Crews. Long term plans call for future campus development to focus on the anchoring buildings. This project relocates direct patient care to the anchoring buildings and the new patient tower to modernize the campus and establish a sustainable foundation for the system's academic medical center, Methodist University Hospital.



SUPPLEMENTAL #1

February 25, 2016
4:06 pm

This additional image shows potential plans for ambulatory growth on the west side of the campus across from the main and ED entrances (shown in red box) as well as a viable site for another patient tower parallel to the new patient tower proposed with this project. The oldest buildings on the east side of campus (highlighted with the large blue box) are marked as a redevelopment zone. The master plans were designed to minimize disruption to patient care and facility operations while planning for sustainability. These are longer term options which will follow CON guidelines and requirements as needed.



Item II.E (Major Medical Equipment)

Number of Existing units before and after project completion (1.a) - In addition to the detailed description on pages 14 and 15, please also briefly summarize the changes to the applicant's MRI, and Linear Accelerator and PET/CT equipment inventory by identifying the number of units as of 02/01/2016 and at project completion (Year 1 of project). Please show the inventory in the table below.

Methodist University Hospital Major Medical Equipment Inventory*

Medical Equipment Units	Methodist University		Methodist Germantown		Methodist North		Methodist South		LeBonheur Children's	
	Now	Year1	Now	Year1	Now	Year1	Now	Year1	Now	Year1
Linear Accelerator	2	3	0	0	0	0	0	0	0	0
MRI[1]	3	4	2	2	2	2	1	1	3	4
PET/CT[2]	0	1	0	0	0	0	0	0	0	0
Total	5	8	2	2	2	2	1	1	3	4

[1] Le Bonheur Children's Hospital has two MRIs and one iMRI for a total of three at the hospital campus downtown. The Le Bonheur Outpatient Center (CN1311-042A) which will be an outpatient department of the hospital is expected to open in 2016 with an approved MRI for pediatric scans. This center is over 10 miles away from campus.in the eastern part of the county.
Methodist University is proposing to add an iMRI to the existing service line for use in the OR.
[2] The Methodist hospital-based PET/CT is currently located in the West Clinic on Union Avenue. The unit at West Clinic on Union will relocate to the Methodist University Campus. See the additional chart below for West Cancer Center below to clarify

Note: for each hospital, please identify #Existing/#at Completion)

The chart for West Cancer Center equipment is also included since this is all Methodist hospital-based equipment.

Medical Equipment Units	West Cancer Center Germantown		West Clinic Downtown (Union Ave)	
	Now	Year1	Now	Year1
Linear Accelerator	2	2	0	0
MRI	1	1	0	0
PET/CT[1]	1	1	1	0
Total	4	4	1	0

[1] The PET/CT at West on Union will relocate Methodist University as part of this project.

Medical Equipment Purchase Costs (3) – The table showing the vendor quotes for the base cost of the units with service agreement costs is noted. Review of the documentation in the attachment revealed that none of the quotes will be effective on the hearing of the application by the HSDA Board Members in May 2016. Please revise or provide an addendum to extend the effective dates through May 2016.

Additionally, there appears to be no documentation that confirms the quotes for the service agreement costs of the 3.0 Tesla MRI unit and the Elekta Radiation Therapy unit. Please document in the form of an addendum to the quotes or a letter from the vendors that identifies the term and cost of the service agreements.

Please see the revised chart from the filed application below for reference. Please see Attachment 3A for revised quotes from vendors with extended effective dates and service agreements for supporting documentation.

Also, please note that as Methodist works with vendors to negotiate prices that costs may decrease. This is already the case for the Linear Accelerator. See revised pages and schedules due to the reduction in vendor price from $2,636,000 to $2,400,000. See Attachment 3B for the revised pages for the filed application. Project costs remain the same since these are estimates for major moveable equipment and the savings will be equipment contingency.

Equipment Type	Equipment	Maintenance (4 years)	Total Cost
iMRI	$ 3,959,767	$ 705,180	$ 4,664,947
Linear Accelerator	$ 2,400,000	$ 950,727	$ 3,350,727
Hybrid Operating Room	$ 1,972,443	$ 375,300	$ 2,347,743

4. **Section C, Need, Item 1 (Project Specific Criteria)**
The responses to the criteria for the PET unit that will be relocated as a part of the project are noted. However, since the applicant plans to add an MRI unit and a radiation therapy unit that will increase the inventory of same in the service area, HSDA staff requests that responses to the criteria for MRI and Radiation Therapy be submitted as a part of the application. All current project specific criteria adopted in the State Health Plan may be found on the HSDA website.

Please see Attachments 4A and 4B for the MRI and Radiation Therapy Criteria and responses.

5. **Section C, Need, Item 3 and 4.B**
Item 3 - The applicant's multi-state service area is noted. Please illustrate the patient origin for the most recent 12-month calendar year period by completing the table below.

Service Area County	2016 Population	2015 Patient Days	As a % of total patient days	Cumulative %
Shelby	949,178	79,561	64.6%	64.6%
Tipton	65,680	1,903	1.5%	66.1%
Fayette	42,805	864	0.7%	66.8%
Lauderdale	27,188	461	0.5%	67.3%
Hardeman	26,164	406	0.5%	67.8%
Haywood	18,019	280	0.4%	68.2%
Dyer	38,301	609	0.3%	68.5%
Madison	100,337	598	0.2%	68.7%
Other TN Counties		2,476	2.0%	70.7%
Sub-total – Tennessee		87,158	70.7%	70.7%
Sub-Total-Other States		36,063	29.3%	100.0%
Total		123,221	100.0%	
Source: 2016 Population data from Department of Health for Tennessee counties in the service area and internal Methodist data				

Item 4B – please identify the incidence rates for heart disease and cancer in the TN Counties noted in the table above.

One of the major priorities of this project is to consolidate currently disjointed clinical services so as to provide an even higher standard of care for our patients. Cancer services, in particular, will be augmented by the establishment of a West Cancer Center on the Methodist University campus. This will be of tremendous benefit to our service area, where the need for cancer services is very evident. In regards to the Tennessee counties within this service area, most counties have an "All Cancers" incidence rate higher than both the state and national averages.

Moreover, with the exception of one county, all of these counties have a racial disparity in terms of cancer mortality, where black patients are dying at much higher rates than white patients. The Methodist University campus is located in an area where racial minorities comprise the majority of the population. Thus this project will provide unprecedented access to high-quality services, like the expanded radiation therapy services and the addition of an iMRI, for example, which will go a long way toward narrowing this racial disparity.

ALL CANCERS INCIDENCE AND DEATH RATES, 2008-2012
METHODIST UNIVERSITY - TENNESSEE SERVICE AREA

Region	Age-Adjusted Incidence Rate (Cases per 100,000)			Age-Adjusted Death Rates (Deaths per 100,000)		
	All	Ages < 65	65+	All	White (including Hispanic)	Black (including Hispanic)
Dyer County, TN	469.3	220.5	1,704.5	183.0	178.6	234.4
Fayette County, TN	477.7	262.9	1,913.3	179.5	155.4	260.0
Hardeman County, TN	512.9	251.7	2,060.6	210.9	190.8	249.1
Haywood County, TN	476.7	226.4	2,053.6	197.8	181.9	222.9
Lauderdale County, TN	476.2	252.4	2,088.2	224.6	233.5	211.0
Madison County, TN	463.2	226.7	1,866.6	180.1	166.1	222.2
Shelby County, TN	472.7	263.6	2,016.1	204.3	174.1	248.9
Tipton County, TN	498.6	243.0	2,154.7	210.3	205.7	235.0
Tennessee	475.3	240.5	2,043.2	193.2	189.0	234.6
United States	465.8	225.2	2,033.8	171.2	170.9	202.0

Source: National Cancer Institute – State Cancer Profiles 2008-2012
Note: Red highlights denote rates above national rates.

Cardiovascular services and critical services will improve with this project as the surgical and diagnostic services are expanded and consolidated in the new patient tower. The prevalence of heart disease in the Medicare populations in the Tennessee service area is higher than national averages for all but one county. High blood pressure and obesity are risk factors that influence the high prevalence of cardiovascular disease. See the charts below.

HEART DISEASE, HIGH BLOOD PRESSURE AND RISK FACTORS
MEDICARE POPULATION, 2012
METHODIST UNIVERSITY - TENNESSEE SERVICE AREA

	Percent with Heart Disease	Percent with High Blood Pressure	Percent Adults with BMI > 30.0 (Obese)
Total Report Area	29.97%	60.62%	33.90%
Dyer County, TN	36.30%	68.94%	35.40%
Fayette County, TN	31.68%	60.89%	32.60%
Hardeman County, TN	35.84%	66.72%	38.80%
Haywood County, TN	35.43%	66.73%	41.40%
Lauderdale County, TN	35.04%	65.94%	38.10%
Madison County, TN	34.12%	65.22%	36.50%
Shelby County, TN	27.77%	58.42%	33.20%
Tipton County, TN	33.84%	61.78%	33.50%
Tennessee	29.22%	58.14%	32.10%
United States	28.55%	55.49%	27.10%
Data Source: Centers for Medicare and Medicaid Services. 2012			

6. **Section C, Need, Item 5 (Service Area Provider Utilization – MRI and Radiation Therapy Services)**
The inpatient utilization of service area acute care providers is noted. Please also summarize the utilization of **MRI and Radiation Therapy providers** by completing tables for each service similar to the table provided below.

SUPPLEMENTAL #1

February 25, 2016

406 pm

Provider Summary, Applicant's TN County Service Area
MRI Summary

County	#Units by Provider Type*	2012 Scans	2013 Scans*	2014 Scans*	% Change '12-'14
Shelby (PSA)	HOSP	70,173	68,880	69,161	-1.4%
	PO	27,064	26,351	26,897	-0.6%
	RPO	6,538	6,737	6,505	-0.5%
	H-Imaging	3,331	2,688	3,680	10.5%
	ODC	2,214	2,563	2,889	30.5%
	ASTC/ODC	1,564	1,287	1,655	5.8%
Shelby County (PSA)		**110,884**	**108,506**	**110,787**	-0.1%
Shelby County Scans per Unit		**2,918**	**2,855**	**2,841**	
Shelby County w/o HOSP St Jude		**102,147**	**100,201**	**102,410**	0.3%
Shelby County w/o HOSP St Jude Scans per Unit		**3,004**	**2,863**	**2,926**	
TN Counties in SSA ((7)	HOSP-Fixed	15,536	14,639	13,205	-15.0%
	PO	7,626	7,552	8,364	9.7%
	HODC	7,027	6,491	7,090	0.9%
	ODC	6,781	8,835	10,676	57.4%
	HOSP-Mobile	389	292	314	-19.3%
TN Counties (SSA)		**37,359**	**37,809**	**39,649**	**6.1%**
TN Counties Scans per Unit		**2,874**	**2,908**	**3,050**	**6.1%**
TN Counties w/o HOSP Mobile		**36,970**	**37,517**	**39,335**	**6.4%**
TN Counties w/o HOSP Mobile Scans per Unit		**3,081**	**3,126**	**3,278**	**6.4%**

Provider Summary, Applicant's TN County Service Area
Radiation Therapy/Linear Accelerator Summary

County	#Units by Provider Type*	2012 Scans	2013 Scans*	2014 Scans*	% Change '12-'14
Shelby (PSA)	HOSP	56,360	51,351	54,584	-3.2%
	ASTC	7,610	6,963	4,647	-38.9%
Shelby County (PSA)		**63,970**	**58,314**	**59,231**	**-7.4%**
Shelby County Scans per Unit		**5,815**	**5,301**	**5,385**	**-7.4%**
Shelby County w/o HOSP St Jude		**59,365**	**54,558**	**54,707**	**-7.8%**
Shelby County w/o HOSP St Jude Scans per Unit		**6,596**	**6,062**	**6,079**	**-7.8%**
TN Counties in SSA ((7)	HOSP	14,985	13,195	-	-100.0%
	HRAD	-	-	14,175	n/a
	RAD	9,338	9,298	6,726	-28.0%
TN Counties (SSA)		**24,323**	**22,493**	**20,901**	**-14.1%**
TN Counties Scans per Unit		**4,865**	**4,499**	**4,180**	**-14.1%**

**Note:Provider type can be abbreviated using the following legend: H (hospital); HOPD (hospital outpatient department); ODC (outpatient diagnostic center); PO (private medical practice; RPO (radiologist physician office). Please check with Alecia Craighead, Stat III, for assistance with data available from the HSDA Equipment Registry*

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7. **Section C, Need, Item 6**

The tables on pages 37 and 38 showing the historical and inpatient utilization of the hospital are noted. Since completion of the replacement ED approved in CN1208-041A, please include the historical & projected utilization of ED visits for the periods indicated in the response (2013 through 2020). In your response, please briefly identify the percentage of total admissions generated through the Emergency Department for the hospital's most recent calendar year period and Year 1 of the project.

Please see the historical and projected ED visits below. Currently, approximately 89% of total admissions are generated through the ED.

	Actual JAR 2012	Actual JAR 2013	Actual JAR 2014	Actual F/S 2015		Proj 2019 Year 1	Proj 2020 Year 2
MUH ED Visits	60,902	62,587	64,724	66,954		67,692	67,354

Please also provide the utilization of the hospital's MRI, Radiation Therapy and PET services by completing the table below.

Applicant's Historical and Projected Utilization

Service	2013	2014	2015	% Change '13-15'	2016 Projected	Year 1	Year 2
PET-MUH and West	2,665	2,730	2,283	-1.4%	2,317	2,457	2,494
MRI	10,524	11,130	11,100	5.5%	11,297	11,979	12,159
Radiation Therapy-MUH & West	21,611	24,739	28,201	30.4%	31,021	32,920	33,578

Source: Tennessee Medical Equipment Registry as of 8/2015 and internal data

Note: The PET in Midtown was relocated and replaced per CN1111-047A from a freestanding Methodist site to the West Clinic on Union Avenue in Midtown as a Methodist hospital-based service in 2013. The Methodist University and West volumes are combined in the chart for simplicity. The PET at the new West Cancer Center was out of service for part of 2015 as it was relocated.

8. **Section C, Economic Feasibility, Item 1 (Project Costs Chart)**

The Chart is noted.

Line A.6 - The contingency cost calculates to approximately 10.6% of the construction cost. Please explain the methodology used to determine same. How does this cost compare to the applicant's experience with other recently CON approved projects involving major new construction?

Contingency costs are calculated in this project as they are in prior applications at approximately 10% of a combined total of construction and site preparation costs – this project is 10.2% based on construction estimates. Experience has shown that 10% is a reasonable construction contingency.

Line A.8 - As requested previously, please identify the amounts included in for the PET and MRI service maintenance costs and document with a valid vendor quote.

See Attachment 3A for Vendor quotes and service agreements.

The total cost before CON filing fee appears to calculate to $279,955,000 in lieu of the $275,955,000 shown in the chart. Please recheck the total provided. If in error, please revise and submit as replacement page labeled 40-R.

See Attachment 8A for a revised project cost which will correct the typo for total cost before the CON filing fee.

The January 17, 2016 letter from the construction contractor is noted. Please identify the name(s) of the primary building and safety codes, AIA guidelines, etc. that will apply to this type of major hospital construction.

Please see the revised letter as Attachment 8B.

9. **Section C, Economic Feasibility, Item 2 (Funding)**
The funding from cash reserves by Methodist Healthcare-Memphis Hospitals with confirmation provided in the February 10, 2016 letter from Mr. McLean, Executive Vice President and CFO is noted. Review of the unaudited Balance Sheet for December 2015 revealed a balance in cash and temporary investments of $990,537,000. Based on funding by the parent organization for recent CON approved projects since 2012 totaling approximately $120 million, are cash reserves sufficient to support the proposed $280 million project going forward? Please briefly discuss.

Cash reserves are sufficient to support the proposed project. The $120M is made up of four projects, one of which is the Methodist University ED Relocation and Renovation project that has been fully funded. The remaining three projects, totaling nearly $90M have been 65% funded, with $30M remaining. There will be an excess of over $960M in cash reserves upon completion of the projects which is sufficient to absorb the proposed project.

10. **Section C Economic Feasibility Item 4 (Historical and Projected Data Charts)**
Historical Data Chart – The chart for Methodist LeBonheur Healthcare appears to apply to the applicant's owner, Methodist Healthcare-Memphis Hospitals. Please clarify.

The Historical Data Chart in the filed application is Methodist Le Bonheur Healthcare. In review of the filed application, the applicant is refiling the funding letter from the CFO to clarify that capital is held at the system or corporate level which is Methodist Le Bonheur Healthcare. See Attachment 10A for the revised letter.

Review of the chart for the parent organization revealed a decrease of approximately 53% from FY 2013 – FY 2015. Please briefly describe the factors that explain the significant decrease during the most recent 3 year fiscal period.

The decrease in Other Revenue / Expense is the main factor that caused a decrease of approximately 53% in net operating income from 2013 to 2015. This balance includes pension liability, interest income, unrealized gains/losses, endowments, and other non-operating revenue/expense. The most significant change was a decrease in the pension liability with similar decreases in interest income and unrealized gains. These changes are all a result of interest rate changes as well as a decline in equity market performance and are not reflective of our healthcare margin. Note the system healthcare margin saw an increase of 74% from 2013 to 2015.

Other Revenue	2013	2015	Difference
Pension Liability	$133,080,000	$5,671,000	$127,409,000
Interest Income	$80,516,000	$8,304,000	$72,212,000
Unrealized Gain	$33,256,000	$1,012,000	$32,244,000

Financial Category	2013	2015	Change in Healthcare Margin
Net Operating Revenue	$1,577,693,000	$1,856,472,000	
Total Operating Expenses	$1,499,751,000	$1,720,747,000	
Healthcare Margin	**$77,942,000**	**$135,725,000**	**74%**

Please provide a Historical Data Chart that illustrates the financial performance of Methodist University Hospital.

Please see Attachment 10B for the Historical Data Chart.

Projected Data Chart – Please complete the table below.

Historical and Projected Financial Performance

Financial Measure	2015*	Year 1 2019
Adjusted Patient Days	213,747	223,139
Gross Operating Revenue	$1,869,858,000	$2,301,926,000
Average Gross Charge	$8,748	$10,316
Net Operating Revenue	$479,617,000	$551,963,000
Operating Expenses	$458,335,000	$556,197,000
Other Revenue	$6,206,000	$6,395,000
Net Operating Income	$27,488,000	($7,839,000)
Capital Interest	$2,213,000	$1,724,000
Net Operating Income (Loss) Less Capital Expenditures	$25,275,000	($9,563,000)
NOI as a % of Gross Operating Revenue	1.5%	(0.34%)

11. **Section C, Economic Feasibility, Item 6.A and 6.B (Charges) and Item 9 (Payor mix)**
Charges- The room and bed charges for the hospital are noted. Please identify the average gross charge, average deduction from charges and average net charge for both the MRI and Radiation Therapy services in Year 1 of the project. Please also compare the Year 1 projected charges for the services to the following:
    - HSDA 1st, median & 3rd quartile range of charges
    - Medicare allowable charges by primary CPT code

Please see current iMRI and Radiation Therapy charges below. There will be no change to the existing charge structure as a result of this project, yet there will be normal unrelated rate increases over the next several years. The Medicare Allowable rates shown below are Payment Rates. The iMRI will be inpatient and paid as a case rate therefore the rate is not shown.

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	CPT Code	Current Rate	Medicare Payment Rate
iMRI			
INTRAOPERABLE BRAIN MRI	70557	$5,491	Case Rate
INTRAOPERABLE BRAIN MRI	70559	$5,491	Case Rate
Radiation Therapy/ Linear Accelerator			
SBRT TX DELIVERY >=1 LESION W/IMAGE GUID	77373	$5,616	$1,541
INTENSITY MODULATED RADIATION TX DLVR SIMPLE	77385	$2,713	$466
INTENSITY MODULATED RADIATION TX DLVR COMPLEX	77386	$2,714	$466
RADIATION TREATMENT DELIVERY 1 MEV >= SIMPLE	77402	$693	$102
RADIATION TREATMENT DELIVERY >=1 MEV INTERMEDIATE	77407	$731	$102
RADIATION TREATMENT DELIVERY >=1 MEV COMPLEX	77412	$725	$179

Based upon the review, the proposed charges are reasonable and comparable to other facilities in the service area. Methodist University Linear Accelerator and MRI charges for 2014 are comparable to similar acute facilities in the Shelby County market. The linear accelerator average charge per procedure is between the median and 3rd quartile. The MRI charge per procedure is slightly higher than the 3rd quartile. There will be no impact to the charge structure due to this project

Gross Charges per Procedure/Treatment
Shelby County Comparisons, 2014

Facility	MRI	LINAC
Methodist University	$3,883	$1,451
Baptist Memorial	$2,749	$998
St Francis Memphis	$4,883	$1,841

Gross Charges per Procedure/Treatment
By Quartiles
YEAR = 2014

Equipment Type	1st Quartile	Median	3rd Quartile
Linear Accelerator	$914.77	$1,118.02	$1,645.78
MRI	$1,632.60	$2,229.43	$3,677.84

Source: Medical Equipment Registry - 8/10/2015

Payor Mix - The total gross revenue shown in the table is $2,241,498 in lieu of the $2,301,926 shown in the Projected Data Chart on page 44. Please clarify. If in error, please revise the table and submit as replacement page 46-R.

The total gross revenue shown in the chart is gross patient revenue of $2,241,498. The other operating revenue is not payor related and is therefore omitted from the payor chart. Please see the charts from the filed application below.

2019 Projected Revenue for Project Data Chart

Revenue from Services to Patients	(in thousands)
Inpatient Services	$ 1,281,950
Outpatient Services	879,220
Emergency Services	80,328
Subtotal Patient Revenue	**$ 2,241,498**
Other Operating Revenue	60,428
Gross Operating Revenue	**$ 2,301,926**

2019 Projected Revenue by Payor

Payor	Revenue (In Thousands)	% of Total Revenue
Medicare	$ 1,109,105	49%
TennCare/Medicaid	$ 311,280	14%
Self-Pay	$231,762	10%
Commercial/Other	$ 589,352	26%
Total	**$2,241,498**	**100%**

12. Section C, Contribution to the Orderly Development of Health Care, Item 3 (Staffing)

The response indicates no changes are planned to the hospital's current staffing. Please provide a table that illustrates the existing direct patient care, clinical support, administration and management staffing complement in Full Time Equivalents for the hospital.

	Projected 2016 FTEs
Direct Patient Care	1,836
Support Services	395
Administration/Management	55
Total FTEs	2,286

Will the project favorably impact growth of the hospital's physician medical staff? Please clarify and illustrate by completing the table below.

Methodist Healthcare has over 1800 credentialed physicians on staff. The state-of-the-art technology and clinical space planned with this project will favorably impact growth of the medical staff. The planned growth is noted in the chart below.

There plans to recruit the following specialties by Year 1 as the tertiary, academic centers are consolidated and expanded. Plus two additional Oncology Surgeons and two additional Oncologists by Year 2.

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Medical Specialty	Year 1
Chief of Cardiology	1
Cardiologist	2
Cardiovascular Surgeon	1
Cardiac Fellows\	2
Chief of Pathology	1
Critical Care Medicine	2
Transplant Surgeon	1
Nephrologist	1
Oncology Surgeon	3
Oncologist	5
Genetic Counselor	2
Radiation Oncologist	2
Physicist	4
Total	27

ADDITIONAL INFORMATION FROM APPLICANT:

Please see Letters of Support for the project in Attachment 13

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ATTACHMENT 2
FINAL REPORT
METHODIST UNIVERSITY
CN1208-041A
ED REPLACEMENT AND RELOCATION

SUPPLEMENTAL #1
February 25, 2016
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TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY
FINAL PROJECT REPORT

Please TYPE or PRINT legibly. Certificate of Need No. CN1208-041

Project Name: Methodist University Hospital - Replace Emergency Department

Owner: Methodist Healthcare - Memphis Hospitals Contact: Carol Weidenhoffer

Description: Replacement of ED on Methodist University Hospital campus. Construct 93,000 sf of new space and renovate 6,200 sf of existing, and replace CT unit.

Total Bed Complement Before Addition: N/A

Total Bed Complement:

What was the Final Completion Date (opened for public use)? September 2014

Was the project completed as certified? ☑ YES ☐ NO
(If not, describe any changes, deletions, and/or additions on additional sheets.)

COST FACTORS		Original Cost Projection	Final Project Cost
A.	Construction and equipment acquired by purchase:		
1.	Architectural and Engineering Fees	$ 1,878,441	$ 1,813,620
2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	$ 80,000	$ 44,150
3.	Acquisition of Site		
4.	Preparation of Site	$ 5,026,250	$ 623,254
5.	Construction Costs	$ 20,019,635	$ 26,490,919
6.	Contingency Fund	$ 2,753,231	
7.	Fixed Equipment (Not included in Construction Contract)	$ 1,083,928	
8.	Moveable Equipment (List all equipment over $50,000)	$ 1,402,500	$ 1,345,502
9.	Other (Specify) Relocate Doctors and West Occupants	$ 1,200,000	$ 323,262
	Subtotal	$ 33,443,985	$ 30,649,705
B.	Acquisition by gift, donation, or lease:		
1.	Facility (inclusive of building and land)		
2.	Building only		
3.	Land only		
4.	Equipment (Specify)		
5.	Other (Specify)		
	Subtotal		
C.	Financing Costs and Fees:		
1.	Interim Financing		
2.	Underwriting Costs		
3.	Reserve for One Year's Debt Service		
4.	Other (Specify)		
	Subtotal		

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D.	Estimated Project Cost (A+B+C)	$ 33,443,985	$ 30,649,705
E.	CON Filing Fee	$ 45,000	$ 45,000
F.	Total Estimated Project Cost (D&E)	$ 33,488,985	$ 30,694,705

FINAL COST† $ 30,694,705 **FINAL FILING FEE‡ $** N/A

If the final project cost is an overrun of the estimated project cost, describe in detail all increases in final costs from those originally projected.

Not Applicable. The project did not have a cost overrun.

For clarification: The ED opened September 2014 but there were final change orders that were part of the project that continued through April/May 2015.

The Final Filing Fee to be assessed on any cost overrun is to be computed at the rate current at the time the project was certified. Below is the outline of the rates from January 1994 through the present.

PERIOD	FEE per $1,000	MAXIMUM - MINIMUM	FINAL FILING FEE
January 30, 1994 through Present	**$2.25/$1,000**	**$3,000--$45,000**	**$2.25/$1,000 Total filing fee (initial plus final) not to exceed $45,000.**

I hereby certify that this information is true to the best of my knowledge, information, and belief, and that supplemental written notification will be filed with the Tennessee Health Services and Development Agency in the event of any change in the information given in this report.

Chief Operating Officer

7/17/15
Date

HF-0055

Revised 1/05 - All forms prior to this date are obsolete.

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ATTACHMENT 3A
VENDOR QUOTES
AND SERVICE AGREEMENTS

SUPPLEMENTAL #1

GE Healthcare

Date: 02-02-2016
Quote #: PRS-002707
Version #: 1

February 25, 2016
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Methodist UT Hospital
1265 Union Ave
Memphis TN 38104-3415

Attn: Mary Carol
1265 Union Ave Suite 700 Memphis
TN 38104-

Customer Number : 87491
Quotation Expiration Date: 04-28-2016

The terms of the Master Purchasing Agreement, Strategic Alliance Agreement or GPO Agreement referenced below as the Governing Agreement shall govern this Quotation. No additional or different terms shall apply unless agreed to in writing by authorized representatives of both parties.

Governing Agreement:	HPG
Terms of Delivery:	FOB Destination
Billing Terms:	80% delivery / 20% Installation
Payment Terms:	NET 30
Total Quote Net Selling Price:	$3,959,766.67

INDICATE FORM OF PAYMENT:

If "GE HFS Loan" or "GE HFS Lease" is NOT selected at the time of signature, then you may NOT elect to seek financing with GE Healthcare Financial Services (GE HFS) to fund this arrangement after shipment.

____Cash/Third Party Loan
____GE HFS Lease
____GE HFS Loan
____Third Party Lease (please identify financing company)

By signing below, each party certifies that it has not made any handwritten modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

Each party has caused this agreement to be executed by its duly authorized representative as of the date set forth below.

CUSTOMER

_____ _____
Authorized Customer Signature Date

_____ _____
Print Name Print Title

_____
Purchase Order Number (if applicable)

GE HEALTHCARE
J Mcnatt 02-02-2016
Signature Date

Product Sales Specialist
Email: J.Mcnatt@med.ge.com
Mobile: +1 865 382 7555
Fax: 865-381-1558

GE Healthcare

SUPPLEMENTAL #1

Date: 02-02-2016
Quote #: PRS-C62407
Version #: 1

February 25, 2016
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Total Quote Selling Price	**$3,959,766.67**
Trade-In and Other Credits	$0.00
Total Quote Net Selling Price	**$3,959,766.67**

To Accept this Quotation

Please sign and return this Quotation together with your Purchase Order To:
J Mcnatt
Mobile: +1 865 382 7555
Email: J.Mcnatt@med.ge.com
Fax: 865-381-1558

Payment Instructions

Please **Remit** Payment for invoices associated with this quotation to:
GE Healthcare
P.O. Box 96483
Chicago, IL 60693

To Accept This Quotation

- Please sign the quote and any included attachments (where requested).
- If requested, please indicate, your form of payment.
- If you include the purchase order, please make sure it references the following information
  - The correct Quote number and version number above
  - The correct Remit To information as indicated in **"Payment Instructions"** above
  - The correct SHIP TO site name and address
  - The correct BILL TO site name and address
  - The correct Total Quote Net Selling Price as indicated above

"Upon submission of a purchase order in response to this quotation, GE Healthcare requests the following to evidence agreement to contract terms.
Signature page on quote filled out with signature and P.O. number.
**********OR**********
Verbiage on the purchase order must state one of the following: (i) Per the terms of Quotation #_____; (ii) Per the terms of GPO#_____; (iii) Per the terms of MPA #_____; or (iv) Per the terms of SAA #_____. Include the applicable quote/agreement number with the reference on the purchase order.
In addition, source of funds (choice of: Cash/Third Party Loan or GE HFS Lease or GE HFS Loan or Third Party Lease through _____), must be indicated, which may be done on the quote signature page (for signed quotes), on the purchase order (where quotes are not signed) or via a separate written source of funds statement (if provided by GE Healthcare)."

SUPPLEMENTAL #1

GE Healthcare

Date: 02-02-2016
Quote #: PR5-C82407
Version #: 1

February 25, 2016
4:06 pm

02-02-2016

GPO Agreement Reference Information

Customer:	Mary Carol
Contract Number:	500043, 500352, 500174, 500072, 500151, 500150, 500277, 1451, 1450, 000903
Start Date:	
End Date:	05/31/2017
Billing Terms:	80% delivery / 20% Installation
Payment Terms:	NET 30
Shipping Terms:	FOB Destination

NOTICE REGARDING MAGNETIC RESONANCE ("MR") PRODUCTS. This notice applies only to the following GE Healthcare products: MR: Discovery MR750, Discovery MR750w, Discovery MR450 and Optima MR450w. GE Healthcare has reclassified several advanced software tools and associated documentation to a GE Healthcare Technical Service Technology package that GE Healthcare feels will bring greater value and interest to our customers. GE Healthcare will continue to provide trained Customer employees with access to the GE Healthcare Technical Service Technology package under a separate agreement. GE Healthcare will continue to provide customers and their third party service providers with access to software tools and associated documentation in order to perform basic service on the CT, MR and NM products listed above upon a request for registration for such access. This will allow GE Healthcare to react faster to the future service needs of GE Healthcare customers. If you have any questions, you can contact your sales Service Specialist.

Offer subject to the Terms and Conditions of the applicable Group Purchasing Agreements currently in effect between GE Healthcare and HealthTrust Purchasing Group includes 500043 (Imaging).

GE Healthcare

SUPPLEMENTAL #1

Date: 02-02-2016
Quote #: PRS-C62407
Ver: 1

February 25, 2016 4:06 pm

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
	1		**Discovery MR750w 3.0T GEM 25.0**			
1	1	S7525AA	Discovery MR750w 3.0T GEM MR System ES Platform The Discovery MR750w 3.0T GEM MR system from GE Healthcare is designed to deliver a comfortable patient-friendly environment while also delivering uncompromised clinical performance and streamlined workflow. The ES configuration includes the system electronics, operating software, imaging software, post-processing software and RF coil suite: • eXtreme Gradient Technology • Acoustic Reduction Technology • OpTix RF Receive Technology • Multi-Drive Transmit & PERFORM 2.0 • Volume Reconstruction Engine • Computing Platform and DICOM • GEM Express Patient Table • GEM Suite - ES Coil Package • Express 2.0 Workflow • ScanTools and ES Tools eXtreme Gradient Technology: The Discovery MR750w GEM delivers high temporal resolution through 3-axis gradient amplifier power supply and efficient gradient coil design as well as high spatial integrity through excellent magnet homogeneity and gradient linearity over a large FOV. In addition, the XRM gradients are	$500,000.00	54.00%	$230,000.00

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

non-resonant and actively shielded to minimize eddy currents, and use an innovative digital control architecture design to deliver high fidelity, accuracy and reproducibility.

- Peak amplitude per axis: 44 mT/m
- Up to 200 T/m/s instantaneous peak slew rate per axis
- Peak current & voltage: 830 Amps, 1650 Volts
- Digital PI feedback loop control
- Maximum FOV: 50cm
- Duty Cycle: 100%

Acoustic Noise Reduction Technology: The Discovery MR750w GEM system features five levels of acoustic reduction technology to deliver an enhanced patient environment.

- Gradient & RF coil isolation
- Acoustic dampening material
- Vibro-acoustic isolation
- Gradient waveform optimization

OpTix RF Receive Technology: The OpTix RF receive chain enables high bandwidth, high channel count reception with improved SNR over conventional MR receiver designs. The MR signal is digitized within the scan room and then optically transmitted to the reconstruction engine in the electronics room increasing SNR for all volume acquisitions.

- Coil input ports: 138

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

- Simultaneous channel/receivers: 32
- Receiver sampling per channel: 80 MHz
- Receiver dynamic range at 1 Hz BW: >165 dB
- Receiver resolution: up to 32 bits
- Digital quadrature demodulation

RF Transmit Technology: The Discovery MR750w GEM system integrates an innovative RF transmit architecture designed to enhance overall image uniformity, and a multi-faceted SAR optimization system.

The MultiDrive RF architecture adjusts/optimizes the phase and amplitude of each RF amplifier output channel that is applied to the 4-port drive whole-body RF transmit coil to enhance RF uniformity and signal homogeneity regardless of patient size and body habitus.

PERFORM 2.0 combines RF body coil design, optimized pulse sequences, detailed predictive SAR modeling during prescription, and real-time SAR feedback and correction during scanning to help ensure high performance across all applications, tailored for each patient.

Computing Platform: The Intel Xeon Nehalem Dual Core Processor computing platform utilizes a parallel, multi-processor design to enable

GE Healthcare

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

simultaneous scanning, reconstruction, filming, post-processing, archiving, and networking. The keyboard assembly integrates an intercom speaker, microphone, volume controls, and emergency stop switch. Start scan, pause scan, stop scan and table advanced to center hot keys are also included.

- 8GB DDR3 Memory
- 146GB SAS disk subsystem
- 24" flat panel LCD with 1920x1200 resolution
- Single tower configuration
- DVD interchange

DICOM: The Discovery MR750w GEM system generates MR Image, Secondary Capture, Structured Report, and Gray Scale Softcopy Presentation State DICOM objects. The DICOM networking supports both send and query retrieve as well as send with storage commit to integrate with PACS archive. Please refer to the DICOM Compliance Statement for Discovery MR750w GEM for further details.

M7000NC (1 unit included in S7525AA) GEM Express Patient Table: The GEM Express table is a mobile patient transport device with an embedded high-density, GEM Posterior RF Array and touch sensitive IntelliTouch land-marking.

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

The fully detachable GEM Express table is easily docked and undocked by a single operator and simple to move in and out of the exam room for patient transport and preparation. These features can be vital in instances where multiple patient transfers can negatively impact patient care or when emergency extraction is required.

The GEM Express table and embedded GEM PA coil are designed to accommodate head-first or feet-first imaging for all supported exams. The table features three high-density coil connection ports: one at each end and one embedded for the GEM PA. Two additional coil connection ports are included in the docking

mechanism.

- Maximum patient weight for scanning: 500 lbs
- Maximum patient weight mobile: 500 lbs
- Maximum patient weight for lift: 500 lbs
- 205 cm symmetrical scan range
- Automated vertical and longitudinal power drive
- Fast longitudinal speed: 30 cm/sec
- Slow longitudinal speed: 0.5 cm/sec
- Integrated arm boards & non-ferrous IV pole
- IntelliTouch & laser land-marking
- Laser alignment land-marking

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

GEM Suite - ES Coil Package: The Geometry Embracing Method - GEM - Suite of coils is designed to enhance patient comfort and image quality while simplifying workflow by ensuring that the geometry of the surface coil matches the geometry of the patient. The ES Coil Package includes:

- T/R Body Coil & T/R Head Coil
- GEM PA, HNU & AA Arrays
- GEM Standard Flex Suite & Positioners
- 3-channel Shoulder Array

M7002AH (1 unit included in S7525AA) The GEM Posterior Array is designed to provide optimal element geometry for each targeted anatomy by using different element geometries for the cervical-to-thoracic spine transition, thoracic and lumbar spine, and the body.

- Elements: 40
- Length: 100 cm; Width: 40cm
- S/I coverage: 100cm head-first or feet-first
- Parallel imaging in all three scan planes
- Head-first or feet-first positioning

The GEM PA is designed to be used in conjunction with the GEM HNU, GEM AA or GEM Small AA (purchased separately), and the GEM PV Array

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

(purchased separately). The GEM PA is invisible to additional surface coils when they are placed directly on top of the surface.

M7000GH (1 unit included in S7525AA) The GEM Head and Neck Unit include the head base-plate and three anatomically optimized anterior arrays: the anterior Neuro-vascular array, the anterior cervical spine array, the anterior open-face array.

The GEM HNU may be positioned at either end of the GEM Express table to support head-first or feet-first imaging and may remain in place for all body, vascular, spine, and the majority of MSK exams. The GEM HNU base plate supports the patient's head, and the Comfort Tilt variable-degree ramp can be positioned under the HNU base plate to elevate the coil to match the patient's head and neck position.

- Elements: up to 28 combined with PA and AA
- Length: 49.5 cm; Width: 38.8 cm
- Height with NV Array: 35.4 cm
- Height with Cervical Array: 32.6 cm
- Height with Open Array: 25.9 cm
- S/I coverage: up to 50 cm with PA and AA
- Parallel imaging in all three scan planes
- Head-first or feet-first positioning

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Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

M7000AK (1 unit included in S7525AA) The GEM Large Anterior Array facilitates chest, abdomen, pelvis, and cardiac imaging. The GEM AA is lightweight, thin and flexible, and pre-formed to conform to the patient's size and shape. With 54 cm of S/I coverage, the GEM AA permits upper abdomen and pelvis imaging without repositioning the coil.

- Elements: up to 36 combined with PA
- Length: 55.6 cm; Width: 67.4 cm
- S/I coverage: 54 cm
- R/L coverage: up to the full 50 cm FOV
- Parallel imaging in all three scan planes
- Head-first or feet-first positioning

M7000SL (1 package included in S7525AA) & M7005BE (1 unit included in S7525AA) The GEM Flex Suite is a versatile set of high-density 16CH receive arrays designed to provide high quality imaging in a wide range of clinical applications. The high degree of flexibility is particularly advantageous when imaging patients that do not fit the constraints of rigid coils. This standard set includes:

- Large Flex Array: 23 cm x 70 cm
- Medium Flex Array: 23 cm x 48 cm
- GEM Flex Interface Module P-Connector

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

• Positioning Devices

M3335LR (1 unit included n S7525AA) The 3-channel Shoulder Array offers the increased signal-to-noise characteristic of phased-array technology, along with a unique sleeve design that delivers exceptional joint-imaging capabilities.

Workflow: Express Workflow 2.0 incorporates features designed to streamline and automate exams.

• In-Room Operator Console and controls

• IntelliTouch land-marking

• Protocol Libraries & Management Tools

• Workflow Manager & Auto Functions

• Inline Processing, Networking & Viewing

• Start Scan, Stop Scan, Pause/Resume Scan

The In-Room Operator Console and dual-sided controls enable interaction with the host computer from the magnet room. The user has direct control or selection of:

• Display of patient name, ID, study description

• Display and entry of patient weight

• Display and entry of patient orientation and position

• Cardiac gating waveform display

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

- EKG lead confirmation with gating control
- Respiratory waveform display
- IntelliTouch Landmarking
- AutoStart
- Display of coil connection and status
- Display of table location and scan time
- Screen saver

Express Exam enables complete control of protocols for prescription, archiving, searching, and sharing. Protocols are organized into two libraries – GE authored and Site authored – and Protocol Notes allow customized notes to be saved with each protocol. ProtoCopy enables a complete exam protocol, from either a library or previous exam, to be shared with a mouse click, and the Modality Worklist provides an automated method of linking exam and protocol information for a patient directly from a DICOM Worklist server.

The Workflow Manager controls the execution of scan prescription, acquisition, processing, viewing and networking and may automate these steps, when requested by the user. Auto Coil Prescription automatically selects the optimum subset of elements for scanning, and AutoStart automatically starts the first acquisition as soon as the

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

technologist exits the magnet room.

Processing steps are automatically completed with Inline Processing once the data have been reconstructed and the images saved into the database. For certain tasks, the user must accept the results or complete additional steps prior to saving the images. These automatic Inline Processing steps can be saved into the Protocol Library.

Inline Viewing allows the user to conveniently view, compare, and analyze images from the Scan Desktop by selecting the desired series from the Workflow Manager.

ScanTools: ScanTools 25.0 and the ES clinical package deliver an expansive portfolio of advanced applications, imaging options, and visualization tools packaged with the system operating software to provide extensive clinical capability and enhanced productivity.

Advanced Neuro Applications:

- PROPELLER 3.0 motion robust radial FSE
- PROPELLER 3.0 FSE-based diffusion imaging
- 3D Cube 2.0 FSE-based 3D imaging
- Dual Inversion 3D Cube imaging
- Spin Echo & Fast Spin Echo Suites
- T1-FLAIR & T2-FLAIR Suite
- Gradient Echo & Fast GRE Suites

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			• Spoiled Gradient Echo & Fast SPGR Suites • Echo Planar, EPI FLAIR & fMRI EPI Suites • EchoPlus with RTFA diffusion imaging • 3D FIESTA & 3D FIESTA-C steady-state imaging • 3D BRAVO IR-prepped fast SPGR imaging • 3D COSMIC modified steady-state imaging • 2D/3D MERGE multi-echo recombined GRE imaging • PROBE PRESS single voxel spectroscopy • BrainSTAT GVF parametric maps • BrainSTAT AIF parametric maps • Ready Brain automated brain exam prescription • DWI Prep Advanced Spine & MSK Applications: • PROPELLER 3.0 motion-robust radial FSE • 3D Cube 2.0 FSE-based 3D imaging • Spin Echo & Fast Spin Echo Suites • Gradient Echo & Fast GRE Suites • 3D COSMIC modified steady-state imaging • 2D/3D MERGE multi-echo recombined GRE imaging • High Bandwidth FSE artifact reduction • Spectral Spatial Fat Suppression			

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Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

Advanced Body Applications:

- Body Navigators pencil-beam diaphragm tracker
- PROPELLER 3.0 motion robust radial FSE
- Spin Echo & Fast Spin Echo Suites
- Gradient Echo & Fast GRE Suites
- 3D Cube 2.0 FSE-based 3D imaging
- 3D LAVA T1 DCE imaging with Turbo ARC
- 2D/3D Dual Echo Fat-Water Imaging
- 3D FRFSE MRCP & HYDRO imaging
- Enhanced SSFSE single-shot FSE imaging
- 2D FS FIESTA steady-state imaging
- Multi-phase DynaPlan
- SmartPrep automated bolus detection
- Fluoro Trigger real-time bolus monitoring
- Respiratory Compensation, Gating & Triggering
- iDrivePro & iDrivePro Plus real-time imaging
- SPECIAL IR Fat Saturation

Advanced Vascular Applications:

- Body Navigators pencil-beam diaphragm tracker
- 2D/3D Time-Of-Flight & 2D Gated Time-of-Flight
- 2D/3D Phase Contrast & Phase Contrast Cine

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

• SmartPrep automated bolus detection

• Fluoro Trigger real-time bolus monitoring

• 3D QuickStep automated multi-station imaging

• Magnetization Transfer& Flow Compensation

• Peripheral & EKG Gating & Triggering

• Respiratory Compensation, Gating & Triggering

Advanced Cardiac Applications:

• Double-Triple IR-FSE with spectral fat suppression

• FastCine FGRE-based, gated multi-phase imaging

• 2D FIESTA Cine steady-state, gated multi-phase imaging

• 3D FS FIESTA steady-state coronary imaging

• iDrivePro Plus real-time inter-active imaging

• Blood Suppression

• Cardiac Navigator diaphragm tracker

• Cardiac Compensation, Gating & Triggering

• Respiratory Compensation, Gating & Triggering

• Cine Paging (128 images/4 windows @ 30fps)

Advanced Imaging Tools:

• ARC & Turbo ARC data-based

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parallel acceleration
- ASSET 3.0 image-based parallel acceleration
- Real Time Field Adjustment for DWI
- Chemical Shift Direction Selection
- 2D/3D GradWarp compensation
- Acoustic Reduction Technology
- IR Prep, DE Prep & T2 Prep
- Full Echo Train & Tailored RF
- Spectral Spatial Fat Suppression
- SPECIAL IR Fat Suppression
- ASPIR Fat Suppression
- Matrix ZIP 512 & ZIP 1024
- 3D Slice 2X ZIP & 4X ZIP
- Square Pixel & Rectangular FOV
- No Phase Wrap & No Frequency Wrap
- Extended Dynamic Range

Advanced Processing & Display:
- Inline Viewing & Inline Processing
- Image Fusion & Image Pasting
- SCIC & PURE surface coil intensity correction
- Multi-planar Volume Reformat
- Interactive Vascular Reformat
- ClariView Image Filtering
- Compare Mode & Reference Image
- Cine Paging (128 images/4 windows @ 30fps)

Advanced FuncTool Analysis:
- ADC maps & eADC mapping
- Correlation Coefficient analysis

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Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			• NEI Negative Enhancement Integral analysis • MTE Mean Time To Enhance analysis • Positive Enhancement Integral analysis • Signal Enhancement Ratio analysis • Maximum Slope Increase analysis • Maximum Difference Function analysis • Difference Function analysis			
2	1	M7000NA	Discovery MR750w Magnet Collector and Vibroacoustic Dampening Kit The MR750w is equipped with GE's most-advanced 3.0T magnet design, high-performance 44 mT/m and 200 T/m/s slew rate gradients, a spacious 70cm patient bore with bright inner-bore lighting, and MultiDrive RF transmit technology delivering performance, productivity and exceptional image quality. GE's Wide-Bore Magnet Design: With GE's active shielding technology and space-age composite design, the lightweight 3.0T magnet minimizes weight while preserving homogeneity and minimizing fringe fields. The result is a 3.0T magnet that does not compromise performance yet can be installed almost anywhere. The magnet's high-homogeneity delivers excellent fat-saturation away from iso-center and ensures image quality over a full 50 cm field-of-view. Coupled with its zero-boil off	$1,250,000.00	54.00%	$575,000.00

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technology and remote magnet monitoring technology, the MR750w 3.0T magnet is designed to provide years of worry-free, reliable, low-cost operation.

In-Room Console (iROC): By consolidating all controls into one place, the In-Room Console (iROC) provides real-time feedback to the operator to improve exam room efficiency. With a high-resolution, color LCD display located just above the MR750w gantry, coil-connection, patient set-up, cardiac and respiratory waveforms make exam preparation a breeze. The iROC provides feedback on:

- Display of patient name, ID, and study description.
- Display and entry of patient weight.
- Display and entry of patient orientation / position.
- AutoStart - initiates automatic scan start.
- Cardiac & Respiratory waveform display.
- IntelliTouch landmarking information, table position, and scan time.
- Coil connection status.

High Performance Whole-Body Gradients: The MR750w incorporates the latest in MR gradient technology with the wide eXtreme Resonance Module (XRMw). XRMw gradients deliver 44 mT/m peak amplitude, up

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			to 200 T/m/s instantaneous peak slew-rate on each axis, and deliver unmatched fidelity, accuracy, and reproducibility (please refer to system datasheet for additional information). They are water-cooled and equipped with integrated thermo-electric cooling panels to provide excellent stability and duty-cycle for gradient intensive applications. The XRMw gradients have been designed with excellent linearity across the 50cm FOV. Utilizing a unique acoustic barrier material, acoustic noise levels are reduced for enhanced patient comfort without compromising imaging performance. MR750w MultiDrive RF Whole-Body RF Coil: The Discovery MR750w system comes with GE's MultiDrive RF transmit technology as a standard system feature. This system features a high efficiency 4-port drive RF body coil and independent RF amplitude and phase control to improve RF signal homogeneity across the field of view. The system features a fully automated optimization to adjust the RF settings for each patient to deliver optimal image quality regardless of patient size or shape.			
3	1	M7005NK	Discovery MR750w 32ch System Electronics The Discovery MR750w 3.0T system incorporates several innovative technologies designed to improve	$1,275,000.00	54.00%	$586,500.00

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			image quality, MR exam workflow and efficiency, and exam consistency at 70 cm. Included in this collector are the technologies that drive the MR750w system including: Volume Reconstruction Engine Architecture: The backbone of any high-channel count system is the reconstruction architecture. The MR750w utilizes the latest multi-core processing engines, acquisition to disk technology, and bulk-access memory to deliver the necessary processing power to reconstruct data from high channel count coils. With 36,000 2D FFTs/sec an impressive volume to ensure you are not hampered in image reconstruction speed. The result is reliable and efficient processing MR data that enhances exam productivity.			
4	1	M7000VA	Vibroacoustic Dampening Kit Material in the Vibroacoustic Dampening Kit can significantly attenuate the transmission of gradient-generated acoustic noise through the building structure to nearby areas, including adjacent rooms and floors above or below the MR suite. If this kit is applied during the installation of a new magnet, no additional service charges are necessary. However, installation of the Vibroacoustic Dampening kit under an existing magnet requires special steps. The steps to prepare the site and steps to install, such as	$14,700.00	54.00%	$6,762.00

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			modifications to the RF screen room, and other magnet rigging, modifications to the RF screen room, and other finishing work, are not covered in the pricing.			
5	1	M3335CD	3.0T Calibration Phantom Kit This 3.0T calibration kit contains a large volume shim phantom, a daily quality assurance phantom, an echo-planar calibration phantom, and associated loader shells.	$17,000.00	54.00%	$7,820.00
6	1	S7505EK	Preinstallation Collector and Cable Concealment Kit The Preinstallation Collector delivers to the site in advance of the magnet and main electronic components. This facilitates the later delivery and installation of supporting electronics. The following are the main components in the Preinstallation collector: • Heat exchange cabinet for distribution of chilled water. • Primary Penetration wall panel for support of the penetration cabinet. • Secondary Penetration wall panel for support of gradient filters, helium cables, and chilled air and water. • Helium cryocooler hose kit. The Cable Concealment Kit accommodates a wide-range of scan room ceiling heights and is designed to provide a clean-look installation by concealing the overhead cabling	$104,000.00	54.00%	$47,840.00

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			from view.			
7	1	M7004NE	Discovery MR750w Scan Room Electronics The MR750w scan room electronics collector includes all of the following: • MultiDrive RF components (cabling and electronics). • Mechanical and electrical docking architecture that interfaces the GE Express patient tables, both GEM and non-GEM tables, to the Discovery MR750w magnet. • RF signal switching hardware and cabling that routes the MR signals received to the respective OpTix receivers.	$425,000.00	54.00%	$195,500.00
8	1	M7000WL	Main Disconnect Panel The Main Disconnect Panel safeguards the MR system's critical electrical components, by providing complete power distribution and emergency-off control.	$12,000.00	54.00%	$5,520.00
9	1	S7524ZS	3.0T Cable Configuration - A To accommodate various electronic and scan room configurations and sizes, the 3.0T has preset lengths of cables and connector kits to speed system installation. This cable collection is compatible with fixed and relocatable building configurations.	$65,500.00	54.00%	$30,130.00
10	1	M3335JZ	English Keyboard Required for our operator console.	Incl.	Incl.	Incl.

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			This keyboard is ergonomically designed to keep your staff comfortable even through the longest shifts. The scan control keyboard assembly has an intercom speaker, microphone, volume controls and emergency stop switch.			
11	1	M3335CA	Calibration Kit Phantom Holder Cart	$3,000.00	54.00%	$1,380.00
12	1	M1000MW	Operator's Console Table Wide table designed specifically for the color LCD monitor and keyboard.	$2,550.00	54.00%	$1,173.00
13	1	R32052AC	Standard service package delivered for the warranty period.	Incl.	Incl.	Incl.
14	1	S7750BF	Spectroscopy Expert Package • PROBE-PRESS and STEAM Single Voxel Spectroscopy • PROBE 2D CSI • PROBE 3D CSI PROBE-PRESS and STEAM Single-Voxel Spectroscopy allows you to non-invasively evaluate the relative concentrations of invivo metabolites. It lets you acquire and display volume localized, water-suppressed 1H spectra in single-voxel mode. This package includes PROBE P (PRESS) and PROBE-S (STEAM) pulse sequences, as well as automated reconstruction, acquisition set-up and graphic prescription of spectroscopic volumes. PROBE 2D CSI expands proton brain spectroscopy capability enabling	$57,000.00	54.00%	$26,220.00

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			simultaneous acquisition of multiple in-plane voxels. PROBE 2D CSI uses the PRESS pulse sequence to acquire and display volume-localized, water suppressed 1H spectra in a multi-voxel mode for the non-invasive assessment of invivo metabolites. Metabolite maps are automatically generated in FuncTool on the operator console. PROBE 3D CSI extends your PROBE-P 2D CSI spectroscopic capabilities by allowing you to perform 3-dimensional multi-voxel acquisitions. Post-processing, including the creation of metabolite maps, is automatically generated with FuncTool Performance Package (included as part of ScanTools).			
15	1	S7525SF	Spectroscopy Elite Package • BREASE BREASE is a single-voxel TE-averaged PRESS sequence that is optimized for mapping the bio-chemical information of breast tissue. The TE averaging eliminates unwanted information from side-bands to ensure clean and simple spectra and streamline interpretation. Optimized prescan and reconstruction algorithms are employed to accurately characterize tissue, especially in areas normally dominated by lipid signal.	$20,000.00	54.00%	$9,200.00
16	1	S7750BD	fMRI Expert Package (on MR console)	$80,000.00	54.00%	$36,800.00

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

- BrainWave RT (Real-Time)
- BrainWave PA (Post Acquisition Analysis)

BrainWave RT provides real-time acquisition, processing and display of functional results. It allows a single technologist to acquire, process and display BOLD (Blood Oxygen Level Dependent) fMRI studies acquired with synchronized stimuli. It is comprehensive, equipping you with all the real-time functionality you need, including paradigm control and development, and real-time display of color activation, overlaid on source EPI images. The main features are:

- 50,000 image storage per series with data acquisition rates up to 20 images per second.
- Display of 2D activation maps overlaid over Echo Planar source images in real time.
- Multiple 2x2 and 4x4 display.
- Optional saving of raw data in research mode for off-line analysis with 200,000 images.

BrainWave Post-Acquisition allows you to produce, from raw fMRI data, 3D brain renderings displaying functional activation. Display alternatives for these maps include cross sectional displays, activation Z-maps and composite paradigm displays. The features include the following:

- Integration into the operator console.

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			• Intuitive graphic user interface for image analysis and display. • Data quality check, motion correction, temporal filtering and spatial smoothing to optimize statistical analysis and mapping. • Multiple regression analysis. • Segmented structural MRI Scan using completely automatic threshold and histogram methods and mathematical morphology techniques. • Rapid retrospective motion correction. • Sophisticated visualization techniques including true volume rendering, light box and orthogonal displays.			
17	1	S7024CB	Neuro Expert Package • eDWI • SWAN • DTI • FiberTrak The eDWI application includes the acquisition sequence and post-processing tools. It is designed to provide high signal-to-noise-ratio diffusion images of the brain and liver with short-acquisition time. Its multi-B feature is designed to provide measurement of apparent diffusion coefficient (ADC) map with reduced effect of perfusion. In addition, "3 in 1" B value combining technique, applies diffusion weighting to all three	$79,125.00	54.00%	$36,397.50

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

gradients simultaneously, helping improve sensitivity. Its smart NEX feature significantly reduces the acquisition time. Inversion recovery has been deployed to provide robust fat suppression.

SWAN is a volumetric 3D acquisition technique that is sensitive to differences in susceptibility between different tissues. This technique acquires multiple-echoes at different echo times to highlight regions with increased T2* (susceptibility-induced) decay. Utilizing multiple-echoes, SWAN generates images with higher SNR when compared with similar techniques that rely on a single echo.

Diffusion Tensor Imaging (DTI) creates contrast based on the degree of diffusion anisotropy in cerebral tissues such as white matter. The DTI method expands Echo planar imaging capability to include diffusion imaging sequence using motion sensing gradient pulses along 6 to 155 orientations in order to generate tensor component images. With the Express Workflow, fractional anisotropy (FA) and Volume Ratio Anisotropy (VRA) maps may be automatically created after image acquisition without any user intervention.

FiberTrak is a host computer post processing tool expands the capability of Diffusion Tensor imaging by generation of 2D color orientation maps, 2D eigenvector

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			maps, and 3D tractography maps from the diffusion tensor image data. The resulting datasets may be easily saved and archived for later use.			
18	1	S7024CC	Neuro Elite Package • 3D ASL • 3D PROMO • FOCUS 3D ASL utilizes water in arterial blood as an endogenous contrast media to help visualize tissue perfusion and provide quantitative assessment of cerebral blood flow (CBF) in ml/100 g/min. The quantitative CBF maps can be generated and stored in DICOM format. 3D PROMO provides a real time 3D navigator based motion correction algorithm correcting for the six rigid body terms where re-acquisition of severely corrupted data provides robust, high quality, motion free, 3D outcomes. 3D PROMO is compatible with both T2 and T2 FLAIR Cube acquisitions. FOCUS delivers a highly efficient method for increasing the resolution in Single Shot DW EPI sequences. The outcome delivers robust high resolution results while removing artifacts typically induced from motion, image backfolding or unsuppressed tissue. In addition, with the higher efficiency of the application, the reduced field of view imaging leads to a reduction in	$123,750.00	54.00%	$56,925.00

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			blurring that translates into an overall improvement to the image quality result. The sequence utilizes 2D selective excitation pulses in DW-EPI acquisitions to limit the prescribed phase encoded field of view.			
19	1	M7001SC	3.0T Silent Suite - Silent Neuro Exam Package - Forward Production The Silent Suite Package includes a complete set of sequences designed to generate high-resolution images which deliver T1, T2, FLAIR, and PD weighted contrasts. The Silenz imaging sequence delivers 3D isotropic images with T1 or PD contrast with sound levels that are within 3dB of the ambient conditions. Newly enhanced gradient waveforms have been employed to minimize the acoustic signature of FSE, 3D Cube, and PROPELLER-based acquisitions to generate T2 and T2 FLAIR weighted images. In addition, the localizer, Prescan, and calibration sequences have been optimized as well to deliver a complete neuro exam at nearly silent levels.	$175,000.00	54.00%	$80,500.00
20	1	M7001SN	3.0T Silent MRA Silent MRA is a 3D acquisition with an Arterial Labeling pre-pulse to deliver the angiographic contrast. The sequence is based on the Silenz imaging sequence which delivers 3D isotropic images at sound levels that are within 3dB of ambient noise.	Incl.	Incl.	Incl.
21	1	M7005DC	Silent PROPELLER Upgrade	Incl.	Incl.	Incl.

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			Silent Suite includes a set of protocols including PROPELLER based acquisitions with Diffusion for high resolution brain exams with and without fat suppression. This allows a full exam to be conducted with less than 11 dB(A) from ambient room conditions.			
22	1	M3335MJ	BrainWave Hardware BrainWave Hardware is the complimentary system to BrainWave Hardware Lite for previous MR systems. It is a supplemental paradigm generation system for functional MRI. Intended for use in conjunction with the BrainWave RealTime image acquisition software, BrainWave Hardware provides a trigger signal to allow synchronization of image acquisition with an external stimulus presented to a subject. BrainWave Hardware includes the following: • Dedicated computer workstation • Equipment rack • Penetration panel waveguide insert • Cedrus patient response pads • Cabling and connectors The computer includes preset paradigms and software tools to generate custom protocols. The visual and auditory output can be coupled to fMRI delivery systems purchased separately from other	$30,300.00	54.00%	$13,938.00

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Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			vendors.			
23	1	E8800DB	3.0T 32-Channel fMRI Head Coil FEATURES AND BENEFIT: • 32-Channel phased array design for high signal-to-noise ratio. • Excellent Z-FOV for imaging the entire head • Parallel imaging with acceleration in all three planes • Superior performance for fast fMRI results • Sliding coil design for ease of patient positioning • Open face for patient viewing and fMRI applications SPECIFICATIONS: • Inner Diameter: 24 cm • Coil Size: 29 cm OD x 30 cm long • Coil Base: 41 cm wide x 48 cm long • Weight: 14 kg with base COMPATIBILITY: • GE 3.0T Discovery MR750 and MR750w systems.	$93,750.00	21.00%	$74,062.50
24	1	M0050SS	3.0T 6-Ch PA Flex Coil Set - Integrated Preamp The 6-Channel Phased Array Flex Coil is indicated for use in conjunction with a 3.0T MR whole body scanner to produce 2D and 3D images. The 6-Channel Flex coil is compatible with GE MR750 and MR750w 3.0T	$68,593.75	54.00%	$31,553.13

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			scanners. This coil has quick disconnect assembly integrated preamps and coil ID. The 3.0T Flex Phased Array coil is a 6-element and 6-channel coil. The coil is low profile, is packaged to maximize positioning capability, and has three visualization openings in each coil. The two coil halves are contained in a flexible foam package. This package has a cleanable, coated surface. The flexibility of the coil makes it easy to wrap the coil around the area of interest. In addition to anterior/posterior positioning, coils can also be positioned laterally around the head. The two coil halves each have one RF cable that connects onto the quick disconnect assembly which plugs into the phased array port on the carriage cover. The coil can be operated while both coils are connected or only when a single coil is connected. Each array is labeled with coil alignment marking for positioning to ensure proper placement on the patient. • Coil Half Dimensions: (L x W x H) 30cm (11.8in) x 30cm (11.8in) x 2cm (0.8in). • Maximum Field of View: 24cm (9.5 in). • Cable Length: 155 cm (61 in).			
25	1	M8074SS	Operating Room Compatible Patient Transfer/Imaging Table - MR450w/MR750w The GEHC MRI Surgical Suite utilizes	$546,516.00	22.00%	$426,282.48

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an operating room patient transfer compatible MR imaging table. This table helps to provide an effective transfer of the patient between the MRI scanner and compatible surgical tables or transports.

- This table is height-adjusted for compatibility with MR450w/MR750w MRI systems.
- Capable of supporting a maximum uniformly distributed load of 227kg (including patient and Coils/Accessories), only for stationary/up position.
- Ability to lock the swivel rotation of one wheel puts the table into a steer lock mode, making it easier to maneuver the table in a straight line while being pushed.
- This table accepts the MR/X-ray compatible patient transfer board with accessories.
- This table allows direct connectivity to various surgical tables and transports and accommodates patient movement on the MR/X-ray compatible patient transfer board.
- This table incorporates auto-latching docking interface assembly enabling docking to compatible surgical table or patient transport by a single operator.
- The Operating Room Compatible patient transfer MR

GE Healthcare

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			imaging table combines the standard diagnostic imaging table capabilities with the additional features of accepting a patient transfer board with accessories and connectivity to compatible surgical tables and patient transports.			
26	1	M0054SS	Magnus Surgical Table Maneuverable Base Column The GEHC MRI Surgical Suite utilizes a Maquet Magnus 1180 surgical table with maneuverable base column that accepts connectivity to the operating room compatible patient transfer MR imaging table and TransMobile surgical transport. • Usable for an overall load of 250kg with appropriate tabletop. • Fitted with deployable wheels which enables movement of column (without patient) to any desired location within surgical theater. • Provides replaceable tabletop feature which allows quick exchange of tabletops. • Accepts triple section MRI transfer compatible tabletops. • Accepts additional Maquet specialty tabletops designed for non-MR transfer specific surgical applications. • Provides automatic docking height and leveling adjustment. • Provided with infrared wireless	$426,562.50	22.00%	$332,718.75

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			hand controller. • Provided with corded hand controller. • Provided with column mounted control panel for override motion control. • Provided with portable charging unit.			
27	1	M0058SS	Magnus 3-Section MR Transfer Surgical Tabletop US The GEHC MRI Surgical Suite utilizes a Maquet Magnus 1180 three-section surgical tabletop with US inch sized accessory guide rails. The tabletop serves to support and position patients for surgical procedures immediately before, during and after the surgical phase. This tabletop attaches to the flush finish floor mount base column M0055SS or maneuverable base column M0057SS or fixed finish floor mount base column M0054SS. This three-section MR transfer tabletop accepts connectivity to the operating room compatible patient transfer MR imaging tables M0010SS, M0053SS, M0074SS and TransMobile surgical transports M0007SS, M0073SS. • Three-section design accommodates wide range of patient positioning flexibility. • Replaceable tabletop technology which allows quick exchange of tabletops. • Smooth and quiet, motor-driven operation.	$463,906.25	22.00%	$361,846.88

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			• Provides trendelenburg, reverse trendelenburg, tilt, flex, reflex, back up/down, head up/down and longitudinal adjustment capability. • Provides specialized attachment points to enable docking of TransMobile patient transport and operating room compatible patient transfer MR imaging table. • Controlled with infrared wireless hand controller or corded hand controller or column override control panel. • Provided with US inch sized (9.54inx28.6in) side guide rail mounts enabling attachment of patient positioning and surgical assist accessories. • Compatible with tabletop transport M0060SS (optional).			
28	1	M0060SS	Magnus Surgical Suite MR Transfer Tabletop Transporter The GEHC MRI Surgical Suite utilizes the Maquet replaceable tabletop technology. A tabletop transport is available (optional) to enable installation, removal and replacement of the three-section MR transfer tabletop. • For use with Maquet Magnus 1180 three section surgical tabletops M0057SS and M0058SS. • Excellent longitudinal and lateral maneuverability of	$42,031.25	22.00%	$32,784.38

GE Healthcare

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			transport with tabletop. • Allows movement of tabletop with patient. • Tracking wheel that can be engaged to allow tight curves negotiation and straight line tracking. • Central brake lever that can be engaged guarantees all wheels are locked when desired.			
29	1	M0071SS	Surgical Suite Transfer Board and Accessories The GEHC MRI Surgical Suite utilizes a patient transfer board that provides capability for the patient on this board to be transferred to the operating room compatible patient transfer MR imaging table, TransMobile patient transport, Maquet 1150 or Magnus1180 MRI transfer tabletop. The patient will be positioned onto the patient pads on top of the transfer board and will remain on the transfer board during the entire patient care process. Maintaining the patient on transfer board minimizes lifting and moving patient between surgery and MR imaging sessions. • The transfer board has the features of being X-ray radiolucent and 3.0 Tesla MRI compatible. • The transfer board is a three-section design enabling the ability to articulate patient into various surgical positions.	$170,156.25	22.00%	$132,721.88

GE Healthcare

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			• The transfer board is provided with patient pads which are placed on top of transfer board. These thermo-modulated special foam core pads adapt to patient's body shape while providing improved pressure distribution. • The patient transfer board accommodates the mounting/attachment of specialized accessories. Accessories can be securely fastened onto eight available mounting points on transfer board, securing with large bolt type fasteners. The transfer board accessories provided are: • Quantity 4 sets of patient restraint straps. • Monitor extension mount and mount bolts. • IV pole and mount bolts. • Quantity 2, patient arm boards.			
30	1	M0059SS	Surgical Suite Positioning Accessories The GEHC MRI Surgical Suite utilizes patient positioning accessory pads which lay on the patient transfer board aiding user with specialty pads for patient comfort and positioning during the surgical procedure. Pads are thermo-modulated special foam core padding that adapts to patient's anatomy while providing improved pressure distribution and aids in patient positioning for surgical procedures.	$12,328.13	22.00%	$9,615.94

GE Healthcare

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			• Quantity 4, semi-circular foam pad 180 x 115 x 465mm. For use as wedge supports to aid in patient positioning. • Quantity 2, tunnel cushion foam pad 650 x 400 x 220mm. Pad is used as lateral patient positioning aid and to help avoid patient's legs against decubitus injury. • Quantity 1, Plexus cushion foam pad 440 x 500 x 100mm. Pad is to help avoid plexus paralyses and provides stabilization of patient's head. • Quantity 2, lateral position foam pad 740 x 500 x 160mm. For use as lateral patient positioning aid. • Quantity 1, leg rest foam pad 640 x 610 x 220mm. Provides elevated rest for patient legs.			
31	1	M0072SS	Surgical Suite Head Rest Extension and Pad The GEHC MRI Surgical Suite utilizes a head rest extension plate which attaches to the patient transfer board providing the capability for the patient on this board to be transferred to the operating room compatible patient transfer MR imaging table, TransMobile patient transport, Maquet 1150 or Magnus1180 MRI Transfer Tabletop. This MR compatible, X-ray radiolucent head rest plate extends the transfer board at the head end by	$2,484.38	22.00%	$1,937.82

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			230mm. The Head Rest attaches to the transfer board with 2 mounting bolts and is provided with thermo-modulated special foam core pad that adapts to patient's head shape while providing improved pressure distribution.			
32	1	M0051SS	MR/X-ray Compatible Surgical Suite Skull Clamp The GEHC MRI Surgical Suite utilizes an exclusive MR/X-ray compatible Skull Clamp custom designed for GEHC by Integra/Mayfield. This 3-point skull fixation clamp provides 7-degrees of adjustment providing the neurosurgeon with flexibility for patient surgical approach positioning. The skull clamp is placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary. In addition, the clamp is indicated for use during utilization of imaging modalities such as intraoperative CT and MR imaging, C-Arm X-ray, and digital subtraction techniques. • The clamp features a detachable torque adjustor with adjustment increments of 20, 40, 60, 80 pounds. • The clamp incorporates removable extension arms, which when used increase	$274,843.75	22.00%	$214,378.13

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

adjustable range in the vertical and "Z" dimensions.

- The base unit securely attaches to the patient transfer board with a two bolt (supplied) securing mechanism.
- The clamp is a 3-point skull fixation device providing 7 degrees of adjustment.
- Skull clamp provides vertical up/down adjustment, arch rotation, arch 360 degree swivel, arch lateral left/right adjustment, arch adjustable "Z" extension and tilt.
- The arch is detachable from the lateral crossbar allowing patient pinning to arch with subsequent attachment to base unit.
- The skull clamp is compatible with MRI scanners including and up to 3.0T field strength and is X-ray radiolucent.
- The skull clamp is provided with individual packaged assemblies for large and small adult skull sizes and an applicator assembly for use during the skull fixation process.
- The skull clamp provides two decagon mounting locations on arch assembly and locking nuts for attachment of surgical navigation systems reference arm assemblies.
- The skull clamp is compatible with options M0052SS Surgical

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			Suite Child Rocker Arm Assembly and M0028SS Decagon Navigation Interface Assembly.			
33	1	M0028SS	Decagon Surgical Navigation Interface Assembly The GEHC MRI Surgical Suite utilizes an exclusive MR/X-ray compatible skull clamp custom designed for GEHC by Integra/Mayfield. Provided as an option to this skull clamp is a decagon surgical navigation interface assembly for the mounting of navigation reference frames by Medtronic and Stryker for use in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary. The decagon surgical navigation interface assembly is indicated for use during utilization of imaging modalities such as intraoperative CT and MR imaging, C-Arm X-ray, and digital subtraction techniques. • The decagon surgical navigation interface assembly is a custom packaged unit that provides two navigation interface assemblies and locking nuts. • The decagon surgical navigation interface assembly is compatible with MRI scanners including and up to 3.0T field strength and is X-ray radiolucent. • The decagon surgical	$14,984.38	22.00%	$11,687.82

GE Healthcare

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			navigation interface assembly is required for systems utilizing Medtronic surgical navigation systems. Note 1: This is optional accessory to M0051SS MR/X-ray Compatible Skull Clamp. Note 2: For Medtronic and Stryker navigation users - MR surgical suite compatible dynamic reference frame attachment arm must be obtained by end-user through Medtronic. Note 3: For BrainLAB navigation users - this option is not needed for BrainLAB navigation based systems, MR surgical suite compatible dynamic reference frame attachment arm and interface assembly must be obtained by end-user through BrainLAB.			
34	1	M0052SS	Surgical Suite Child Rocker Arm Assembly The GEHC MRI Surgical Suite utilizes an exclusive MR/X-ray compatible skull clamp custom designed for GEHC by Integra/Mayfield. Provided as an option to this skull clamp is a child sized rocker assembly for use in open and percutaneous craniotomies as well as spinal surgery when rigid fixation on children is necessary. The child rocker arm assembly is indicated for use during utilization of imaging modalities such as intraoperative CT and MR imaging, C-Arm X-ray, and digital subtraction techniques.	$19,687.50	22.00%	$15,356.25

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			• The child rocker arm assembly is a custom packaged unit that provides a pre-assembled short shaft rocker arm with hex engagement and locking knob for child fixation. • The child rocker arm assembly provides a pre-assembled long threaded engagement shaft with piston and thumbscrew for child fixation. • The child rocker arm is compatible with MRI scanners including and up to 3.0T field strength and is X-ray radiolucent. Note: This is an optional accessory to M0051SS MR/X-ray Compatible Skull Clamp.			
35	1	M0032SS	Coil Accessories Kit for MRI Surgical Suite The GEHC MRI Surgical Suite utilizes 6 channel flex coils for imaging. Provided for use with these coils is an accessory kit. This kit contains transfer board mounts, extensions and cable securing locking mechanisms. Utilization of cable securing mechanism ensures coil cables are trouble-free if emergency patient egress is initiated.	$4,391.00	22.00%	$3,424.98
36	1	M0061SS	MR Surgical Suite Operator Manual in English, French, German, Italian, Spanish, Portuguese, Dutch, Japanese, Korean, Chinese, and Polish.	Incl.	Incl.	Incl.

SUPPLEMENTAL #1

GE Healthcare

Date: 02-02-2016
Quote #: PRS-C62407
Ver 406#pm 1

February 25, 2016

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
37	1	E8911SA	GE Discovery MR450 and Discovery MR750 Heat Exchangers - 70kW (30 Tons) - Seismically Certified Heat Exchanger Cooling for your GE Healthcare MR system has never been so easy. GE Healthcare has partnered with the Glen Dimplex Group, a world leader in cooling systems, to offer heat exchangers designed to meet the needs of your Discovery MR System. Now you can look to GE Healthcare for your entire MR purchase and support. This heat exchanger is highly reliable and the only unit verified to perform with the new platform of GE Healthcare MR systems. As part of your integrated GE Healthcare solution, you'll work with a single contact throughout the whole installation. A Project Manager of Installation will help with building layout, room designs, delivery and installation - every step until your system is ready to scan. Our team will work seamlessly with architects, contractors and your internal team to help ensure timely, cost-effective completion. Once your cooling system is running, you'll get fast, highly-skilled service support managed through GE Healthcare - with the same quality and response time you expect from your MR system. FEATURES AND BENEFITS	$64,313.00	21.00%	$50,807.27

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

- Designed to provide stable fully dedicated cooling for your MR system's needs
- Water/glycol outdoor-air-cooled heat exchangers to support your highest exam volumes and your full range of diagnostic procedures
- Redundant fluid pumps with automatic switchover let you keep operating with no loss of cooling even if one pump goes down
- Quad compressor, dual tandem refrigeration circuit design saves on energy while your system smoothly transitions through the 10% to 100% heat load capacity cycles of patient scanning and idling
- Quiet operation between patient exams and overnight - ideal for facilities in residential areas
- Comes with installation support, installation visits, preventative maintenance visit and 1 full year of parts and labor warranty
- Installation support includes: support through GE's Project Manager of Install, GE's Design Center, technical support from the Glen Dimplex company, two (2) installation visits
- Comprehensive and quality service rapidly delivered

GE Healthcare

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

through our CARES service solution

- 65 gallons of 100% glycol concentrate for complete system filling and diluting
- Wall mounted remote display panel provides the ability to monitor the system's operation and indicates possible system errors
- Filter kit with flow meter helps to ensure purity of water prior to entry to the MR system
- Highly recommended that Vibration Isolation Spring Kit (E8911CJ) be added for systems that will be rooftop mounted

SPECIFICATIONS

- Net Cooling Capacity: 70 kW / 30 Ton
- Maximum Coolant Flow: 35 gpm (132 l/m)
- Coolant Outlet Temperature: 48 F (8.9 C)
- Coolant Temp Stability: E 1.8 F (E1.0 C)
- Max Coolant Pressure : 70 Psi (4.8 Bar)
- Refrigerant: R407C
- Ambient Temp Range: -20 to 120 F (-30 to 50 C)
- Condenser Air Flow (Approx): 18,000 Cfm
- Tank Capacity: 100 gal (378 l)
- Flow Meter Range: 4-40 gpm
- Filters: 50 micron cartridge

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

filters

- Supply Voltage: 460v / 3 phase / 60 Hz
- Coolant Connections: 2" NPTF
- Overall Size (L x W x H) 44" x 136" x 84.5"

COMPATIBILITY:

- GE Discovery MR450 1.5T MR system
- GE Discovery MR750 3.0T MR system

NOTES:

- Item is NON-RETURNABLE and NON-REFUNDABLE
- Standard bolt anchoring is recommended over vibration isolation spring mounts in earthquake prone regions

Seismically Certified Heat Exchanger: Unit for regions where seismic activity is of concern, or, is otherwise mandated by state regulation, to be designed to pass seismic shake table testing. These chillers have been tested and certified in accordance with certification method 'ICC-ES AC-156', to remain fully operable after testing was completed. In addition, the units have passed the California Office of Statewide Health Planning & Development (OSHPD) board certificataion with pre-approval #

GE Healthcare

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			OSP-0169-10.			
38	1	E8804SB	Medrad Spectris Solaris EP MR Injection System Medrad Spectris Solaris EP MR injector for use use in all MR scanner field strengths up to and including 3.0T. Optimized touch-screen for fewer keystrokes, KVO (keep vein open) allows patient to be prepared before beginning the scan. Larger 115 ml saline syringe for longer KVO or multiple flushes. Includes cables and starter kit...E NOTE: GE is responsible for unpacking, assembly, and installation of equipment. Medrad will be available for technical assistance by phone at (412)767-2400. An additional charge will apply for on-site installation assistance. Medrad will be responsible for operational checkout, final calibration, in-service of the equipment, and initial applications training. Please contact the local Medrad office two weeks in advance of installation.	$49,375.00	21.00%	$39,006.25
39	1	E8819ED	Expression is specifically designed to withstand demanding environments with strong magnetic fields, Expression delivers the highest quality results, increased patient comfort and safety, and improved productivity with a lifetime of reliability. • Six-color waveform capability -	$140,000.00	21.00%	$110,600.00

GE Healthcare

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

two ECG, SpO2, EtCO2 and two IBP - provides and easy to see overview of patient status

- The cleanest and safest ECG information available, thanks to proprietary Advanced Gradient software, for any clinical magnet up to and including 3.0 Tesla
- Wireless SpO2 monitoring uses a digital signal to ensure precise values for saturation and fast acquisition, even on pediatrics.
- Precise EtCO2 measurement with waveform fill helps you make more informed decisions when monitoring respiratory gas.
- Patient body temperature monitoring allows you to provide the same standard of care in the MRI suite that you offer in the OR by allowing rectal, esophageal or surface temperature measurements.
- The smart battery management system provides a full eight hours of life on a single charge for each wireless module. The monitor displays the remaining battery life for the base unit, display and each module. A remote battery charger charges up to four depleted batteries at one time.
- Large, tilting 12-inch color screen makes patient monitorig

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			as effortless as possible with a complete picture of patient status including ECG, SpO2, EtCO2, invasive pressures and Active Trend Arrows - that can easily be viewed from a distance • Expression's 360 alarm light is positioned on top of the monitor, so you can be alerted to check the patient's condition even when you cant bear the alarm or when you arent in front of the screen Numbers and graphs are color-coded and easy to read, enabling fast decision making. Open menus dont block all vitals so you can continuously monitor the patient. • Using the innovative, quick-set mount, you can easily remove the display and place it in a more convenient location in seconds. • Navigation is "dial-and-select" simple. Just turn the large control knob and click on the vital sign for more targeted menu options.			
40	1	E8819EF	Expression is specifically designed to withstand demanding environments with strong magnetic fields, Expression delivers the highest quality results, increased patient comfort and safety, and improved productivity with a lifetime of reliability.	$140,000.00	21.00%	$110,600.00

GE Healthcare

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

- Six-color waveform capability - two ECG, SpO2, EtCO2 and two IBP - provides and easy to see overview of patient status
- The cleanest and safest ECG information available, thanks to proprietary Advanced Gradient software, for any clinical magnet up to and including 3.0 Tesla
- Wireless SpO2 monitoring uses a digital signal to ensure precise values for saturation and fast acquisition, even on pediatrics.
- Precise EtCO2 measurement with waveform fill helps you make more informed decisions when monitoring respiratory gas.
- Patient body temperature monitoring allows you to provide the same standard of care in the MRI suite that you offer in the OR by allowing rectal, esophageal or surface temperature measurements.
- The smart battery management system provides a full eight hours of life on a single charge for each wireless module. The monitor displays the remaining battery life for the base unit, display and each module. A remote battery charger charges up to four depleted batteries at one time.
- Large, tilting 12-inch color

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			screen makes patient monitorig as effortless as possible with a complete picture of patient status including ECG, SpO2, EtCO2, invasive pressures and Active Trend Arrows - that can easily be viewed from a distance • Expression's 360 alarm light is positioned on top of the monitor, so you can be alerted to check the patient's condition even when you cant bear the alarm or when you arent in front of the screen Numbers and graphs are color-coded and easy to read, enabling fast decision making. Open menus dont block all vitals so you can continuously monitor the patient. • Using the innovative, quick-set mount, you can easily remove the display and place it in a more convenient location in seconds. • Navigation is "dial-and-select" simple. Just turn the large control knob and click on the vital sign for more targeted menu options.			
41	1	E8819EG	Expression Wireless Display	$19,750.00	21.00%	$15,602.50
42	1	E8803BE	Physician's Chair with Padded Arms Physician's chair has padded arms for comfort and comes in a charcoal gray color that blends with any environment. Chair adjusts from	$899.00	21.00%	$710.21

GE Healthcare

SUPPLEMENTAL #1
Date: 02-02-2016
Quote #: PR5-C82407
Ver 1
February 25, 2016 4:06 pm

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			16.75 in. to 21 in. (42.5 cm x 53.3cm) and is only for use in the MR Control Room. Weighs 45 lbs.			
43	1	E8806FA	MR Skull Pins Starter Kit	$33,500.00	21.00%	$26,465.00
	1		**NonProducts**			
44	1		Rigging in iMRI NTE $9999.00	$9,999.00	0.00%	$9,999.00

Quote Summary:

Total Contract List Price:	**$6,831,996.14**
Total Discount: (42.04%)	**($2,872,229.47)**
Total Extended Selling Price:	**$3,959,766.67**
Total Quote Net Selling Price	**$3,959,766.67**

(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price Includes Trade In allowance, if applicable.)

SUPPLEMENTAL #1
Date: 02-02-2016
Quote #: PRS-C62407
Version #: 1
February 25, 2016
4:06 pm

GE Healthcare

Options

(These items are not included in the total quotation amount)

Item No.	Qty	Catalog No.	Description	List Price	Discount	Ext Sell Price	
45	1	M3335LL	3.0T 8-Channel Brain Array - Invivo The 8-Channel Brain Array is designed for high-definition MR brain imaging on 3.0T HDxt or MR750 systems. Its 8-element quadrature, phased-array design provides 24 cm of coverage, enabling both anatomical and vascular imaging of the brain. The coil is optimized for use with ASSET acceleration for enhanced neuro imaging.	$49,000.00	54.00%	$22,540.00	X_____
46	1	W0123MR	iMRI Basic Training Two days onsite consultation. Two 4-consecutive day visits for vendor simulation. Six onsite follow-up visits to supervise surgical cases and/or perform simulation reviews. Simulation reviews must be delivered in conjunction with a surgical case. Excludes MRI system training.	$66,000.00	0.00%	$66,000.00	X_____

(Quoted prices do not reflect state and local taxes if applicable.

SUPPLEMENTAL #1

February 25, 2016
4:06 pm

GE Healthcare

Date: 02-02-2016
Quote #: PR3-C62407
Version #: 1

Item No.	Qty	Catalog No.	Description	List Price	Discount	Ext Sell Price

Total Net Selling Price Includes Trade In allowance, if applicable.)

SUPPLEMENTAL #1

February 25, 2016
406 pm

Addendum to Quotations

GE Healthcare

This Addendum to Quotations ("Addendum") is entered into as of February 19, 2016, by and between Methodist UT Hospital with an address at 1265 Union Ave., Memphis, TN 38104-3415 ("Customer") and General Electric Company, by and through its GE Healthcare division with an address at 9900 Innovation Drive, Wauwatosa, WI 53226 ("GE Healthcare").

WHEREAS, GE Healthcare has provided Customer with those certain Quotations identified and attached hereto as Exhibit A (each, a "Quotation" and collectively, the "Quotations",) concerning GE Healthcare's desire to sell to Customer, and Customer's agreement to purchase from GE Healthcare, certain GE Healthcare products and/or services listed on each such Quotation in accordance with the terms and conditions set forth on each such Quotation (each such Quotation, an "Agreement" and collectively, the "Agreements"); and

WHEREAS, the parties now desire to amend and/or supplement the Agreement in accordance with the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the premises and the representations and mutual undertakings hereinafter set forth, and for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree to the foregoing and as follows:

1. The Quotations are amended by modifying the Quotation Expiration Dates to read as follows:

"06-30-2016"

2. Entire Agreement. In the event of any conflict between the terms and conditions of this Addendum on the one hand, and the Agreement on the other hand, the terms and conditions of this Addendum shall govern and control. Except as otherwise expressly provided in this Addendum, the parties agree that all provisions of the Agreement are hereby ratified and agreed to be in full force and effect and are incorporated herein by reference. This Addendum and the Agreement contain the entire agreement among the parties relating to the subject matter herein and all prior proposals, discussions and writings by and among the parties and relating to the subject matter herein are superseded hereby and thereby.

3. Form of Payment. Customer's form of payment is as follows:

Initial to indicate form of payment:
(If potential for a lease exists, GE HFS or otherwise, select lease)

_____ Cash* _____ Lease _____ HFS Loan
If leasing please provide name of finance company below:

_____

*Selecting cash declines option for GE HFS financing

IN WITNESS WHEREOF, Customer and GE Healthcare have caused this Addendum to be executed by their duly authorized representatives as of the day and year first above written.

Methodist UT Hospital

Signature: Jami Peden

GE Healthcare

Signature: _____

SUPPLEMENTAL #1
February 25, 2016
406 pm

Print Name: Jamie Peeler
Title: Capital Purchaser
Date: 2.19.16

Print Name: _____
Title: _____
Date: _____

Exhibit A

No.	Quotation No.	Date
1	PR6-C62165 v1	February 2, 2016
2	PR2-C68173 v1	February 2, 2016
3	PR3-C62407 v1	February 2, 2016

Please see attached.

SUPPLEMENTAL #1

February 25, 2016
4:06 pm

GE Healthcare

Diagnostic Imaging Service Proposal

METHODIST HEALTH SYSTEM

Quote expires on 6/1/2016

GE Healthcare is excited about partnering with you for all of your Diagnostic Imaging service needs. The following is a preliminary quote for your imaging equipment. The quote is for budgetary purposes and contains only a general description of the proposed Service offerings. Final pricing and terms will be solely those contained in an executed Agreement.

Equipment	Offering	Options	Features	Annual Amount
GE MR 3.0T DISCOVERY MR750w (M#17B)	AssurePoint Standard	INCLUDED: • GE SUPPLIED COILS • GEM SUITE INCL. PATIENT TABLE • ILINQ RESPONSE TIME: 30 MIN. • SPECTROSCOPY • SYSTEM USAGE: UNLIMITED EXCLUDED: • CHILLER COVERAGE • PERIPHERAL DEVICES • Printers • UNINTERRUPTED POWER SUPPLY • WORKSTATION • MAGNET MAINTENANCE & CRYOGEN	• Remote Console: Excluded • FE Coverage Weekdays: MON-FRI, 8AM-9PM • FE Coverage Weekend: NO COVERAGE HRS • FE Onsite Response Time: 4-Hours • iCenter • InSite Response: 30 • InSite/Tech Phone Support • PM Coverage HOURS/DAYS: MON-FRI, 8AM-9PM • Repair Parts: Included, Next Day 10:30 AM LST-MR • Software Upgrades and Updates: Software and Quality Updates • TiP Answer Line • TiP-Ed Online(TV) Subscription • Uptime Commitment: 97%	$131,400
GE MR MR MAGNET MAINTENANCE AND CRYOGEN (MSC28Z)	Magnet Maintenance and Cryogen	INCLUDED: • MAGNET: 3T EXCITE AND HIGHER: HD/HDX..	• FE Coverage Weekdays: MON-FRI, 8AM-9PM • InSite/Tech Phone Support • Parts Shipping: Included, Next Day 10:30 AM LST-GENERAL	$44,895
TOTAL:				$176,295

Please call me with any questions:
901.356.7664

Respectfully,

Dan Germanotta
GE Healthcare Services Account Manager

SUPPLEMENTAL #1

February 25, 2016

4:06 pm

ELEKTA

Quotation Number: 2015-112631-MB

Quotation Date: January 9, 2016

Valid Until: June 30, 2016

Prepared For:

Genia Nipp
Methodist Healthcare - Memphis
PO BOX 41058
Memphis, Tennessee 38174-1058
US
(t) (901) 516-0625
(f) (901) 516-0649

Currency: USD

Prepared By:

Donald Wilkymacky
Regional Manager

400 Perimeter Center Terrace, Suite 50
Atlanta, GA 30046
(t) (513) 467-6220
(c) (513) 503-8287
don.wilkymacky@elekta.com

Elekta is pleased to submit the following Quotation for the products, software licenses, and/or services described herein at the prices and terms stated.

Elekta Versa HD	**Total Products List Price:**	$8,688,395.29
	Total Offer Price:	$2,400,000.00

The price under this Quotation reflects a discount of $6,288,395.29 USD. If customer is an entity that reports its costs on a cost report required by the Department of Health and Human Services or a state healthcare program, the customer must fully and accurately report any discount that has been provided by Elekta under the final agreement between the parties in the applicable cost report and provide information upon request by the Secretary of Health and Human Services or a state agency. A reportable discount may be set out above or exist in the form of undertakings made by Supplier elsewhere in this Agreement.

Subject to Elekta, Inc. Terms and Conditions or those previously negotiated.

State, local, VAT and other taxes, and import/export licenses are not included in this Quotation

SUPPLEMENTAL #1
February 25, 2016
406 pm

ELEKTA

Quotation Number: 2015-112631-MB Quotation Date: February 22, 2016 Valid Until: June 30, 2016

Scope of Supply

Qty	Description
1	**Elekta Versa HD™** Versa HD™ provides: • Digital accelerator with exclusive cover set design; • Agility™, Elekta's integrated multi-leaf collimator that provides full field high resolution beam shaping (5mm at isocentre), a 40 x 40cm treatment field and effective leaf tip speed of up to 6.5cm/sec, capable of covering multiple targets with interdigitation and island shapes; • 6MV and 10MV flattened energies delivered as standard; • A broad spectrum of delivery techniques from 3D Conformal Radiotherapy to IMRT, VMAT and SRT techniques; • XVI, offering 2D and 3D kV image guidance for advanced soft tissue visualization supporting image guided treatment workflows, XVI Software options VolumeView™, MotionView™ and PlanarView™ are included; • iViewGT™, offering 2D MV imaging capability supporting image guided treatment workflows.
1	**ExacTrac Goalpost Set** Versa HD™ compatible Goalposts in combination with Brainlab ExacTrac System.
1	**Versa HD standard cover set.**
1	**Integrity™ R3.2 control system software** Integrity is the latest generation of Elekta's fully digital treatment control system software for systems with Agility™. Integrity is built on the latest LynX OS platform and is the monitoring and control foundation of Elekta treatment delivery systems. Integrity additionally supports Continuously Variable Dose Rate, dynamic and VMAT deliveries.
1	**Hardware Upgrade Kit - Integrity™ R3.1**
1	**High Dose Rate Mode Hardware Upgrade Kit**
1	**Integrity ™ 3.1 Software Upgrade Kit**
1	**Linac Seismic Kit USA** Compliant to Californian Building Code.
1	**XVI Seismic kit**
1	**15 MV High Energy Photon**
1	**6MV High Dose Rate Software License** High Dose Rate Mode provides flattening filter free beam delivery of 6MV beams at dose rates up 1,400 MU/min, as well as reduction in scatter, lowering whole body radiation doses.
1	**10MV High Dose Rate Software License** High Dose Rate Mode provides flattening filter free beam delivery of 10MV beams at dose rates up to 2,200 MU/min, as well as reduction in scatter, lowering whole body radiation doses.

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1 **6 MeV Electron Energy**

1 **9 MeV Electron Energy**

1 **12 MeV Electron Energy**

1 **15 MeV Electron Energy**

1 **U.S.A. Electron Flatness**
Electron flatness according to U.S.A. standards, optimized at 100 cm.

1 **Standard Set of Aperture Plate Electron Beam Applicators**
Field sizes:

- 6 x 6 cm, SSD 95 cm
- 10 x 10 cm, SSD 95 cm
- 14 x 14 cm, SSD 95 cm
- 20 x 20 cm, SSD 95 cm

Fitted with spring loaded touch guard, coded end frames and electrical connection to linear accelerator latch mounting system enables easy and rapid attachment.

1 **Customer Data Match**
The option of matching one or more new Elekta machines to each other and/or to an Elekta machine already installed on a customer site. The match is carried out during production of the new machines and the match is made to the factory data recorded in production for the existing Elekta machine.

1 **Wedge Factor Match**
The option of matching the wedged profiles and wedge output factors of one or more new Elekta machines to each other and to an Elekta machine already installed on a customer site. The match is carried out during production of the new machines and the match is made to customer data supplied from the existing Elekta machine.

1 **VMAT CAT (Volumetric Arc Therapy Customer Acceptance Test)**

1 **Response™ Gating Control System for Digital Accelerators**
Response provides a seamless interface that supports automated gated treatment delivery for a range of delivery techniques on the Elekta Digital Accelerator. The gating signal can be provided by a validated external motion management system, such as the Active Breathing Coordinator™.

1 **SYNERGISTIQ ™ Software License**
Enables the XVI functionality to support SYNERGISTIQ. SYNERGISTIQ integrates MOSAIQ® and Elekta Synergy® into a consolidated and synchronized user interface.

1 **Software Media Pack, SYNERGISTIQ™ Clients**

1 **kiloVoltage Cone-beam CT Hardware for Versa HD™**

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1 **40kW kV generator - 480V**
The integrated 40kW kV generator provides multiple settings control via the XVI software. Acquisition parameters are configured within the preset protocol function in the XVI software, and is user configurable. The generator and X-ray tube have been optimized for the 3D VolumeView™ imaging, as well as the 2D radiographic type exposures of PlanarView™ and MotionView™.

1 **Control System hardware for XVI R5.0.3**
The XVI control system is a high specification PC which supports all aspects of the IGRT process including 2D, 3D and 4D kV image acquisition, reconstruction, and analysis using a suite of registration functionality.

1 **Base XVI License**
The XVI 5.x base license includes the following features as standard:

- PlanarView™: 2D kV radiograph mode
- MotionView™: 2D kV fluoroscopic mode
- VolumeView™: 3D kV volumetric imaging mode
- Segmental MotionView™ and VolumeView™: Pause/Restart 2D fluoro or 3D volumetric acquisitions manually.

1 **Intrafraction Imaging License**
Provides the ability to acquire kV images during the delivery of an MV treatment field. Intra-fraction imaging allows you to:

- Acquire images (2D fluoro) for a specified time, and then move directly into a 3D volumetric acquisition.
- Acquire a 3D volumetric image during conformal, IMRT or VMAT MV deliveries to measure intrafraction movement.
- Perform Intra-fraction 3D or 4D volumetric imaging and registration per arc during dual (or multiple) arc procedures, allowing table corrections in between arcs.

1 **Symmetry™ License**
Symmetry is primarily indicated for respiratory motion management. It offers a unique 4D IGRT online solution that is correlated to internal organ movement. It facilitates for the planned dose to be delivered to the volume where the target spends most of its time in. This allows for margin reduction and baseline shift compensation, supporting treatment deliveries during free-breathing with no surrogates. The use of Symmetry does not require planning on a 4D reference CT.

1 **Critical Structure Avoidance**
Critical Structure Avoidance allows the registration of two separate areas of anatomy, utilizing both the clipbox and the Shaped Registration Region of Interest. XVI software will calculate the relationship of both areas of anatomy to the proposed correction vectors and alert the user if the target has moved closer to the critical structures due to anatomical changes. The user can then choose to select a compromise between the two areas, or send the patient for re-planning.

1 **3D Automated Seed Match License**
Offers an optimized 3D registration algorithm to register implanted markers, without compromising on 3D volumetric information.

1 **Distributed Review**
Distributed Review allows the sending of XVI CBCT data to MOSAIQ® for review at any MOSAIQ® workstation, as well as the primary XVI workstation.
Pre-requisites:

- Distributed Imaging/Treatment
- DICOM CT Export (+/- Auto DICOM CT Export).

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1 **Distributed Imaging**
Distributed Imaging allows the transfer a patient between XVI systems without having to prepare the registration settings on the secondary XVI system, through MOSAIQ®.

1 **Elekta XVI Basic Calibration Kit - Bearing Phantom Assembly**
Specially designed geometric calibration phantom for kV to MV isocentre alignment. Suitable for the XVI system with the iBEAM® evo couch top.

1 **Couchtop Adaptor kit for QA Phantom**
Single ball phantom table top adapter kit. This attachment supports the single ball bearing phantom which is used to calibrate the XVI imaging software to the mechanical isocenter. Fits the iBEAM®, iBEAM® evo, HexaPOD™ evo and Connexion™ couchtops.

1 **Kit, XVI Daily QA Phantom**
Daily QA Phantom for kV and MV projection imaging and kV VolumeView™ checks Laser and lightfield coincide additionally Spreadsheet for recording and analyzing trend results.

1 **XVI Water Calibration Kit**
Water phantom calibration kit for XVI calibration. It provides a reduction in CBCT image ring artefacts in addition to image quality improvements.

1 **VolumeView™ Contrast phantom**
QA phantom to enable measurement of high resolution and contrast resolution and other image quality parameters of the VolumeView images acquired on the XVI workstation.

1 **2D Image Quality Phantom**
Image quality phantom use for 2D kV image quality to determine the low contrast and spatial resolution of XVI 2D images (PlanarView™ images). This test tool is used for the 2D image quality of the Customer Acceptance Test for XVI and can be used to monitor image quality over a period of time.

1 **DICOM 4D export**
4D DICOM export allows the user to export to a third party system the CBCT data as generated by Symmetry™ of:

- Average phases
- All phases
- Single phase.

1 **Archive and retrieve to network**
Performs automatic archiving of patient images to a pre-defined network location, outside of MOSAIQ®. Archiving can be scheduled, and the network location can be specified at will. The same tool performs retrieval of files from the same location.

1 **Versa HD™ iViewGT™**
This kit contains all of the components for iViewGT including;

- A MK 6 imaging control system cabinet with the iViewGT software R3.4.1. pre-installed.
- A rigid and fully retractable slim line MV imaging detector arm with a large, square active detector area and wide lateral and longitudinal movement adjustments. The arm has automatic and manual arm movements and is fully interlocked.

1 **iViewGT™ Amorphous Silicon detector panel**

1 **iViewGT™ R3.4.1 Installation Kit**

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1 **iViewGT™ R3.4.1 Software License**

1 **iViewGT ™ R3.4.1Software License Collation**
Third Party License toolkit necessary for supporting iViewGT.

1 **Remote Retraction of the iViewGT™ detector - 30M**
This kit allows Remote Retraction of the iViewGT detector from the Function Key Pad.

1 **DICOM 3.0 software interface for image transfer**
The international standard interface protocol for network transfer of medical images.

1 **iViewGT™ IMRT Verification Software License**
This software expands existing iViewGT functions to verify multiple segment beams for IMRT. The iViewGT image acquisition is triggered automatically and the image taken depends on whether the user selects single, multiple or movie image.

1 **Template Matching Software License**
The template matching option enables the user to compare the portal image with a nominated reference image for any set-up error. The set-up error is measured by matching visible anatomy and the field edge on the referenced image with the portal image. The user can move the templates to provide an image displacement.

1 **Patient Auto Select Software License**
This enables the prescription selected on the Linac to automatically select or create that patient record on iViewGT™ or iViewC™ using the iCom-Vx protocol. In addition, images will automatically be acquired and stored in the iViewGT / iViewC database without further operator intervention.

1 **Software License Image Approval**
This allows the user, assigned with the 'review' permission, to approve or disapprove any image within iViewGT™ or iViewC™.

1 **Las Vegas Calibration Phantom**
The Las Vegas phantom is a device that is used to check image quality of a portal imaging device at different megavoltage energies both at acceptance and as part of the corrective maintenance procedure.

1 **HexaPOD evo RT System with iGUIDE 2.1**
This HexaPOD evo RT System / iGUIDE 2.1 a robotic patient positioning system with 6DOF to correct patient positioning misalignments. This System is dedicated for the usage in combination with the Brainlab ExacTrac System.It consists of:

- HexaPOD evo Module
- iBEAM evo Extension 415
- iBEAM evo Extension 650
- iBEAM evo Frameless Extension (for Brainlab Array)
- iBEAM evo Indexing Bars
- Hand Held Control
- Enable Switch Board
- iGUIDE 2.1 Workstation
- 2 Monitors, 2Keyboard and 2 Mice (Workstation / Terminal)
- iGUIDE Tracking System
- Reference Frame Set.

1 **HexaPOD™ evo RT System Integration License**
This licence package will provide the following integration features:

- Interface to MOSAIQ for automated patient ID and treatment site loading for departments using MOSAIQ 2.5 or higher.
- Control of Precise Table with iGUIDE for Systems with Integrity 3.2.

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1 **iBEAM® evo Extension 650**
The iBEAM evo Extension 650 is designed to support the patient's upper body and extends off the end of the iBEAM evo Couchtop by 650 mm, thus allowing for treatment of the prostate of very tall patients.

1 **iBEAM® evo Couch Adapter**
Allows mounting head fixation system with a hook & latch mechanism.

1 **BodyFIX® 14 System Stereotactic Frameless for indexed table tops**
This is a system for indexed table tops. It's ideal for immobilization and accurate repositioning of the patient from planning to treatment delivery. It is the solution for use with IGRT for dose escalated hypofractionated treatment delivery. It is designed for the treatment of the total body. The stereotactic target positioner and localizer is not included.

2 **BodyFIX® 14 BlueBAG™ plus HIP 700x1825/50L**

2 **BodyFIX® 14 BlueBAG™ plus HIP 700x2025/60L**

2 **BodyFIX® 14 BlueBAG™ plus HIP 850x2025/80L**

1 **Active Breathing Coordinator™**
Active Breathing Coordinator provides non-invasive, internal immobilization of anatomies affected by respiratory motion. Active Breathing Coordinator supports automated assisted breath-hold gating of the MV beam in conjunction with the Response gating interface, as well as manual gating capability without Response.

- The ergonomic design provides flexibility and ease of use.
- The laptop can be used on the trolley or off taken out and used in the treatment control room.
- The basket gives ample room for the mouthpiece, nose clips and other items.
- The display, keyboard and mouse on the trolley can be moved and used patient side.
- The trolley includes storage positions for items like the mouth-piece fixation and patient control switch, for ease of storage and transport.

1 **Mouth Piece and Filter Kit (standard; qty 20)**
Kit of 20 Mouthpiece & Filter assemblies to replace those discarded after use. For use with the Active Breathing Coordinator™.

1 **Active Breathing Coordinator™ Trolley Keyboard**
The Active Breathing Coordinator trolley keyboard should be purchased locally to suit the needs of the user using the specifications detailed in PRT 0127.

1 **Active Breathing Coordinator™ Laptop Specification**
The Active Breathing Coordinator laptop should be purchased locally using the specifications detailed in PRT 0128.

1 **3L Spirometer Calibration Syringe for Active Breathing Coordinator™**
3 liter manual Spirometer Calibration Syringe for quality assurance of the Active Breathing Coordinator.

1 **Active Breathing Coordinator™ R3.0 Media Kit**

1 **Cat 5 Network cable 30 meters**
Required to connect the Active Breathing Coordinator™ system in the treatment room to the laptop in the control room.

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1 **Coded shadow tray assembly - Short**
Provides a means for attaching X-ray shadow blocks onto the head of the Linear Accelerator or Simulator. Comprising:

- Shadow tray assembly with hook and latch mounting, and multi-way plug connector
- Two removable parallel transparent Perspex™ trays, one of which may be coded.

1 **Beam Block Tray - Star Pattern**
Lexan beam block tray with holes in a star pattern. Trays are designed with threaded, removable plugs for the coding of each block. Specially designed for use with the Elekta shadow tray assembly.

1 **Hook and Latch Magnification Graticule**
Solid Frame Port Film magnification graticule that attaches directly to the Linac, taking the place of the coded shadow tray, thus providing more clearance between the patient and the accessory. Used in treatment verification for situations where simultaneous fitment of blocking tray is not required.

1 **Electron Beam Field Shaping System**
For use with Electron applicators from Elekta and allows the user to easily provide Electron Beam field shaping. The system comprises:

- A Universal leveling template with an adjustable arm for securing styro-foam inserts- Set of five (5) rubber molds compatible with Elekta Electron applicators
  - 6cm x 6cm
  - 10cm x 10cm
  - 14cm x 14cm
  - 20cm x 20cm
  - 25cm x 25cm

Provided as part of the system is one (1) Hot Wire Cutter.

4 **19-inch Control Room LCD Monitor**

1 **IMKM**
The In-room Monitor and Keyboard function provides the operator with access to all clinical and service functions available at the control console from inside the treatment room.
Comprising:

- Cable switching connectors for attaching the in-room monitor to the treatment control system.

1 **In-room Monitor, Keyboard and Mouse Local Procurement Specification**

1 **AQUA Version 1.0 base license.**
AQUA is a QA management system designed to integrate devices such as treatment delivery, imaging and quality assurance equipment in routine use within today's radiation therapy departments, irrespective of vendor, including:

- Linear accelerators
- Quality assurance equipment
- CT simulators and other imaging systems
- Brachytherapy equipment
- Gamma Knife® and other radiosurgery machines

AQUA provides a web-based database for easy monitoring and maintenance of all machine QA processes across the clinic, or multiple sites, allowing centralized data management and remote access. Providing a full suite of workflow-orientated machine QA tasks, AQUA monitors regular scheduled tests to confirm that machines are operating within specifications and are fit for patient therapy. With real-time alerts to areas that require immediate attention, AQUA detects machine compliance and performance issues before they

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affect clinical service, increasing confidence in machine quality and safety.
The base license includes integration of up to two devices.

2 **AQUA additional device license.**
This license requires the customer to have AQUA site license (TRT 7401) and can only be ordered in addition to a new or existing site license. Order one license per additional device.

1 **Delivery Parameters Log File Convertor**
Enables a user to upload log files and have them converted into csv format.

1 **IntelliMax™ Intelligent Agent**
This License provides only the IntelliMax Intelligent Agent license. Any provision of services relating to the use of data collected by the Agent (via the IntelliMax Enterprise) should be negotiated as part of the Service Contract between the Customer and the BU/distributor. IntelliMax Intelligent Agent requires a dedicated PC. Provision of this PC must be negotiated between the Customer and the Elekta BU/Distributor. A specification of the PC can be obtained from your Elekta representative. IntelliMax Intelligent Agent also requires a direct internet connection to the Agent PC opening secure port 443 (https).

1 **Extender Cards**
Extender cards for fault diagnosis on the Electrical Interface Module (EIM).

1 **ExacTrac Hardware CITB Kit - 15m**
The CITB-ET enables communication between ElektaLinac and Brainlab ExacTrac System. The provided cable length is 15m.

1 **Turbo Starter Kit for Linear Accelerators**
Ancillary equipment required for the installation and maintenance of any Precise Digital Accelerator. Comprising:

- Rotary vacuum pump
- Turbo molecular pump attachment for rapid pump down times and higher roughing vacuum.

1 **Room Lasers, Green, Remote**
Set of 4 green room lasers with remote control adjustment. Comprising 3 crosshair and 1 line sagittal laser. Featuring fine lines (< 1mm), high precision adjustment at the isocenter and stable mounting bracket. Inclusive of switchable (110v to 240v) power supply and universal main adaptor.

2 **Clinical academic course: IMRT/VMAT**
The objective of this clinical program is to present the steps required to implement IMRT/VMAT for routine treatment on Elekta's linear accelerators.

Target groups
Radiation oncologists
Medical physicists
Dosimetrists
Radiation Therapists/Radiographers

Content:

- Commissioning the linear accelerator and treatment
- planning system for IMRT/VMAT
- Acquisition of beam data
- Dosimetry and stability of beam segments of small MU and dimensions
- Methods to establish the appropriate margins for IMRT/VMAT
- Inverse planning methods for IMRT/VMAT
- QA tools for IMRT/VMAT delivery
- Demonstrations performed on Elekta linear accelerators

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- 2-day course.

2 **Clinical academic course: SBRT**

Objective:
This advanced clinical training program is designed to present the processes required to implement Sterotactic Radiation Therapy (SRT) / Radiosurgery (SRS) utilizing Elekta Axesse™ and other Elekta linear accelerators stereotactic capabilities.

Target groups

- Radiation Therapists/Radiographers
- Dosimetrist
- Radiation Oncologists
- Physicists

Content:

- Understand dose selection, fractionation and planning techniques
- Become familiar with imaging requirements (pre/post treatment)
- Practice setup and verification
- Observe and discuss delivery of SRT/SRS
- Increase confidence to implement SRT/SRS into routine clinical practice
- Provide theoretical background to Stereotaxy and dose escalation/ hypofractionation
- Demonstrate the use of Elekta SRT systems for target localization
- Practical session in patient setup, positioning and immobilization
- Dose selection, fractionation and planning techniques

Training centres

- 2-day course held at European centre in collaboration with Elekta.
- 2-day course held at: Wake Forest School of Medicine, Winston Salem, NC , USA

Pricing Does Not Include

- Airfare
- Hotel
- Travel related expenses.

1 **Applications Training for Standard Therapy on the Desktop**
The 2-day Standard Precise Desktop Course (travel time inclusive) provides training for 4 Radiation Therapists in the clinical use of the Precise Desktop Digital Linear Accelerator. Successful participants will be equipped with the knowledge and skills to operate the system effectively. The course does not provide training in the principles or techniques used in Radiation Therapy.

1 **Applications training for iViewGT™**
The 3-day iViewGT training course (travel time inclusive), provides training for 4 radiation therapists in the clinical use of the iViewGT imaging system. Successful participants will be equipped with the knowledge and skills to operate the system effectively. The course does not provide training in the principles or techniques used in radiation therapy.

1 **XVI Applications Training**
The 4-day XVI training course (travel time inclusive) provides training for Radiation Therapists in the clinical use of the X-ray Volume Imaging portion of the Elekta Digital Accelerators. Successful participants will be equipped with the knowledge and skills to operate the system effectively. The course does not provide training in the principles or techniques used in Radiation Therapy, CT, or Diagnostic Imaging. This course is given at the customer site for a maximum of 4 users.

1 **HexaPOD™ evo RT System Training**

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The 2-day HexaPOD evo RT CouchTop and iGUIDE® course (travel inclusive) provides training for 4 radiation therapists in the clinical use of the HexaPOD evo RT CouchTop and iGUIDE software. Successful participants will be equipped with the knowledge and skills to operate the system effectively. The course does not provide training in the principles or techniques used in radiation therapy.

1 **BodyFIX® Training**
The 1-day BodyFIX system course provides training for 4 radiation therapists in the clinical use of the BodyFIX system. Successful participants will be equipped with the knowledge and skills to operate the system effectively. The course does not provide training in the principles or techniques used in radiation therapy.

1 **Linac Labor Warranty**

1 **Standard Rigging & Handling**
Basic rigging of Linac to first floor or ground floor location. Elekta will provide the necessary crew to offload, uncrate, rigging and machinery moving required to set system as per plan, and remove debris. Basic rigging excludes use of a crane or rigging down an elevator shaft.
Standard Rigging includes:

- Make one pre-installation site visit and delivery project management.
- Drill holes for equipment fasteners
- Supply a 12,000 lb. capacity forklift during the off-loading procedure
- Stage and uncrate the Linac machine, move all components into the facility, and set as directed.
- Remove and dispose of all packaging that will not be reused.
- Transport the base, gantry and beam arm into the facility/bunker on transport trolleys supplied by Elekta.
- Set the base frame in place (Elekta will level).
- Set the gantry drum onto the base frame.
- Set beam arm into the gantry.
- Install counterweight holder and stack the counterweights.
- Supply a manual gantry lifting system to perform aforementioned setting activities and all necessary tools.-

Supply a crew, including a rigging supervisor.

- Include the cost of all associated resource and expenses, including related travel time.
- Complete all rigging activities in a single day.

Standard Rigging excludes:

- Crane service. - Elevator, or shaft deliveries.
- No clear access to the building (exterior).
- Interior obstruction en route to treatment room.
- Any shoring needed to protect the structure from the weight of the system.
- Any shoring and/or plating needed to build temporary dock or landing area for the unit.
- Extra-long delivery routes, distances in excess of 150' from offload site to the treatment room.
- Overtime, weekend, premium time, unless Weekend Rigging selected.
- Additional travel expenses should the project exceed the time allotted in this scope for reasons beyond Elekta or our contractor's control.
- Additional man-hours, manpower, travel expenses, or equipment required due to delays caused by incorrect site preparation, waiting time, or delays not caused by Elekta or our contractor will be itemized and billed to the customer at then current rates.

1 **Open Air Graticule**
The Open Air Graticule is intended to be used for Radiation Therapy to project a scale of defined increments on port film images which can aid in treatment setup and verification. The Open Air Graticule does not require the use of a shadow tray holder and can be attached directly to the head of the Precise Treatment System or SL Linac. It consists of two wires delineating the X & Y axis of the treatment field. This model of graticule is ideal for MLC customers and especially those using Elekta's iView & iViewGTTM. Because the open air graticule has a minimal transmission factor, with Physic's approval, the customer does not have to re-enter the treatment

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room after the port film to deliver the treatment. Please see product User manual for specific treatment information.

1 **Elekta Site Marketing Program**
Elekta's Strategic Marketing and Referral Techniques (SMART) program provides a comprehensive array of general and technology-specific marketing tools and resource materials to help you cultivate your investment. If purchased separately via a third party, this package could be valued at $12,000.00 USD.
Following is a content overview of the program:

- Elekta Site Marketing Templates & Materials Package - CD-ROMs contain PowerPoint presentations, suggested copy, brochures, videos and templates to help your center market to patient populations and referring physicians, as well as product images that can be used to produce brochures, patient education pieces, advertising, etc. Templates and design source files may be customized by your center to align with your specific outreach or branding.
- Secure Website - Following a brief registration process, you will have 24-hour marketing support via secure online access to the most current SMART images, video materials, tools and templates, guidebooks and tutorial material. Download design files or templates to facilitate customization and meeting time-sensitive deadlines, or video files for use in consultation, on targeted website landing pages, or as calls-to-action. Quickly reference guidebooks, suggested marketing timelines and strategies, when and where you need them.
- Educational Outreach - Periodic WebEx presentations offer virtual learning opportunities that support practice growth objectives within evolving market strategies. Email publications keep you informed on best practices within traditional and virtual marketing channels. Additional opportunities include live events to coincide with regional / national meetings, such as Elekta's Oncology Users Meeting, to provide updates on getting the most out of your SMART tools, as well as evolving market trends.

1 **Aperture Plate Electron Beam Applicator 25 x 25 cm**
Fitted with spring loaded touch guard, coded end frames and electrical connection to linear accelerator.
The X-ray diaphragms are then set automatically to the optimum position.
A unique hook and latch mounting system enables easy and rapid attachment.

1 **Applications training for Active Breathing Coordinator™**
A 2 day on site Applications training for ABC is given for a maximum of 4 operators. This course ensures that the operators are confident and able to use the ABC and all purchased licensed options safely and efficiently The course does not provide training in the principles or techniques used in radiation therapy.

1 **Elekta Versa HD™ - Optional XVI Cassettes**
Provision of additional XVI collimators, in Elekta Versa HD colours, for Imaging. Includes:

- VolumeView cassettes: L10, M2, L2
- XVI Cassette holder.

1 **Linac Installation**

1 **Drayage**

1 **Closed Circuit TV System - Color**
The standard CCTV system consists of two Samsung SNP-5321 (1.3 Megapixel HD) dome-shaped color cameras and two pan/tilt/zoom control mounts allowing the operator full control of both cameras. An 18.5 inch flat screen monitor is also provided and supports a resolution of up to 1360 x 768.

1 **Intercom system for patient and radiographer communication**
The ASK-4® 501-TLI-CF is a single zone audio monitoring system with 2-way talk/listen capabilities. It consists of a remote speaker/microphone and audio base station with built-in microphone and speaker.

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1 **Non-Standard Request**

Please refer to Exhibit G for full details of the Non-Standard Request included in this offer.

1 **Medical Gases SF6 for Installation and Service**
Includes:

- 44-liter cylinder for SF6 gas
- 115 lbs of SF6 gas
- Regulator
- Delivery.

1 **Medical Gases Nitrogen for Installation and Service**
Includes:

- 16-liter cylinder for Nitrogen (N2) gas
- Nitrogen (N2) gas
- Regulator
- Delivery.

1 **A Frame for Installation/Service**
Includes:

- A Frame
- Trolley
- Hoist (pulley)

Delivery Note: Not required if iBeam is in place.

1 **Power Distribution Unit for Elekta® Linear Accelerator - 480 Volt Input**
The PDCU incorporates a transformer, output circuit breakers, filtering for high frequency noise, distortion, and transient pulse suppression, in one cabinet. This reduces site preparation costs and complexity for the customer.

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ONCOLOGY | BRACHYTHERAPY | NEUROSCIENCE | SOFTWARE | SERVICES

Elekta is pioneering significant innovations and clinical solutions for treating cancer and brain disorders. We provide intelligent and resource-efficient technologies that improve, prolong and save patient lives.

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Currency: USD

Elekta is pleased to submit the following Quotation for the products, software licenses, and/or services described herein at the prices and terms stated.

Total Products List Price:	$950,725.00
Total Products Discount:	$0.00
Total Offer Price:	$950,725.00

The price under this Quotation reflects a discount of $0.00 USD. If customer is an entity that reports its costs on a cost report required by the Department of Health and Human Services or a state healthcare program, the customer must fully and accurately report any discount that has been provided by Elekta under the final agreement between the parties in the applicable cost report and provide information upon request by the Secretary of Health and Human Services or a state agency. A reportable discount may be set out above or exist in the form of undertakings made by Supplier elsewhere in this Agreement.

Subject to Elekta, Inc. Terms and Conditions or those previously negotiated.

State, local, VAT and other taxes, and import/export licenses are not included in this Quotation

SUPPLEMENTAL #1
February 25, 2016
406 pm

ELEKTA

Quotation Number: 2016-125653-MB Quotation Date: February 22, 2016 Valid Until: June 30, 2016

Scope of Supply

Qty	Description
5	Service for Versa HD

SUPPLEMENTAL #1

February 25, 2016

PHILIPS HEALTHCARE
A division of Philips Electronics North America Corporation
22100 Bothell Everett Highway
P.O. Box 3003
Bothell, Washington 98041-3003

Quotation #: 1-1EN38XN	**Rev:** 3	**Effective From:** 23-Feb-16	**To:** 30-Jun-16

Presented To:
METHODIST HEALTHCARE UNIVERSITY HOSPITAL
1265 UNION AVE
MEMPHIS, TN 38104-3499

Tel:

Alternate Address:

Presented By:
Brad Behanna
Account Manager
Tel: (615) 585-6739
Fax:

Kevin Fultz
Regional Manager
Tel:
Fax:

Date Printed: 23-Feb-16

Submit Orders To:
22100 BOTHELL EVERETT HWY
BOTHELL WA 98021
Tel: (888) 564-8643
Fax: (425) 458-0390

The Service information contained in this Quote is subject to a separate service proposal.

IMPORTANT NOTICE: Health care providers are reminded that if the transactions herein include or involve a loan or discount (including a rebate or other price reduction), they must fully and accurately report such loan or discount on cost reports or other applicable reports or claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, such as may be required by state or federal law, including but not limited to 42 CFR 1001.952(h).

SUPPLEMENTAL #1

February 25, 2016

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Quote Solution Summary

Line #	Product	Qty	Price
	100247 Allura Xper FD20 OR Table	1	$1,972,443.00
		Equipment Total:	$1,972,443.00

Solution Summary Detail

Product	Qty	Each	Monthly	Price
100247 Allura Xper FD20 OR Table	1	$1,972,443.00		$1,972,443.00
SVC0130 Protection POS			$7,818.75	

The Service information contained in this Quote is subject to a separate service proposal.

Buying Group: **HEALTHTRUST PURCHASING GROUP** **Contract #:** **500005**

Addt'l Terms:

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

Payment Terms: 0% Down, 80% Upon Delivery, 20% Due When the Product is Available for First Patient Use, Net due 30 days from date of invoice

Quote Summary

100247 Allura Xper FD20 OR Table

Qty	Product
1	NNAE968 FD20_C ORT FlexMove
1	NNAE159 30Fr/sec Extension
1	NNAE853 FlexVision_XL 8 Input Package
1	NCVC490 Maquet ORT integration kit
1	NCVA801 Table APC
1	NCVA695 FD Rotational Angio
1	NCVA694 Subtracted Bolus Chase
1	NCVA693 FD Dual Fluoro
1	NCVA672 FD SmartMask
1	NCVA101 Peripheral X-ray Filter
1	NCVC319 HeartNavigator R2
1	NCVB878 Interventional Tools Hardware
1	NCVA590 Real time image link
1	NCVA116 3D RA Control for Xper Module
1	NCVB775 FlexV XL xperHD for 3rd p. MCS
2	980406041009 Rad Shield w/ Arm (Contoured) 61X76
1	989801220158 Mark 7 Arterion, Table Mount
1	989801220273 Ceiling Track w/Column & Handle Ext
1	989801220281 25 kVA Fluoro only UPS - UPC
1	Third Party Item Hybrid OR Comps:lts,booms,dspys, vid int
1	Third Party Item Flexvision boom
1	Third Party Item Maquet Table

Options

Qty	Product
1	NCVB868 CX50 Video and UI coupling
1	NCVC132 EchoNavigator R2
1	NCVA092 Lab Reporting
1	NCVA781 Dicom Print compose
1	NCVA258 CO2 View Trace Software
1	NCVB171 3D-RA R.6
1	NCVB168 3D Roadmap
1	NCVB167 MR/CT Roadmap

SUPPLEMENTAL #1

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Quote Summary

100247 Allura Xper FD20 OR Table

Options

Qty	Product
1	FCV0569 Coupling to Video Switching
1	NCVB947 XL screen video-share slaving
1	NCVB591 2ND REF for FlexVision XL
1	980406190009 PIVOTING TABLE-MOUNTED RADIATION SHIELD
1	989801220202 CORE Precision Guided Therapy System
1	989801220211 CORE™ Control Pad Option

100247 Allura Xper FD20 OR Table

System Type: New
Freight Terms: FOB Destination
Warranty Terms: Part numbers beginning with two (2) asterisks (**) are covered by a System 12 Months Warranty. All other part numbers are third (3rd) party items.
Special Notations: Contingencies must be removed 120 days before scheduled shipment to assure delivery on specified date. Any rigging costs are the responsibility of the Purchaser.
Additional Terms:

Line #	Part #	Description	Qty
1	**NNAE968	FD20_C ORT FlexMove	1

Allura Xper FD20 ORT FlexMove monoplane system is a state of art X-ray imaging system that can be customized to support a wide range of applications including peripheral, abdominal, cerebral, thoracic, cardiac and non-vascular interventional and diagnostic procedures. The system is delivered without the Xper Table and a Maquet Magnus operating table must be added to the system. Table side user interface modules are now mounted to the pedestal.

The Allura Xper with FlexMove option allows placement in a normal operating theater.

- The new ceiling construction enables the use of Laminar Airflow.
- In case no imaging is needed, the system can be parked in the corner, which allows a normal operating area when doing open surgery and enables the user to make full use of the lab.
- The head-end side of the patient is still available for anesthesia and therefore not blocked by the Allura system.

GEOMETRY

The Allura Xper FD20 FlexMove Stand

The Allura FlexMove stand is a stable assembly of a C-arm and a ceiling suspended L-arm. The ceiling suspended L-arm provides the following advantages:

- The new ceiling construction allows the system to be steered over the patient by using a joy-stick which prevents table panning which is not wanted in a lot of cases.
- The system can be positioned behind a physician or someone of the staff which gives them all the space they need around the patient and can be moved in a simple manor whenever needed.
- The new ceiling construction allows the system to be moved around the patient and be brought in from any position.
- When a minimally invasive procedure has to convert to open surgery, the system can easily be moved out of the way.
- The Allura Xper system with FlexMove takes only limited amount of space around the table and for that reason has limited impact on the workflow of the physicians and staff in the room.
- The FlexMove option is available for two different ceiling heights being 2900mm and 3100mm.

The stand has the following capability:

100247 Allura Xper FD20 OR Table			
Line #	**Part #**	**Description**	**Qty**

- The L-arm can be rotated and can be moved in longitudinal direction allowing a three-sided patient approach and total body coverage.
  - L-arm rotation around the patient table: +90, 0, -90 degrees.
  - FlexMove coverage: Y stroke 4400mm, X-stroke 2600mm
- The Allura stand allows a very wide range of projections, including PA and AP imaging.
- In the head position (0 degrees position, L-arm parallel to patient table):
  - C-arm rotation range (degrees): 120 LAO to 185 RAO
  - C-arm angulation range (degrees): 90 CA to 90 CR
  - (Full angulation capability determined by patient position)
- In the side position (+90 / -90 degrees position, L-arm perpendicular to patient table):
  - C-arm rotation range (degrees): 90 LAO to 90 RAO
  - C-arm angulation range (degrees): 185 CA to 120 CR or 120 CA to 185 CR
  - (Full angulation capability determined by patient position)
- The stand provides fully motorized fast movements with variable and configurable maximum speed.
  - Variable C-arm rotation speed, up to 25 degrees per second
  - Variable C-arm angulation speed, up to 18 degrees per second
- L-arm rotation and longitudinal movement: motorized and manual
- C-arm depth is 90 cm
- The FD20 Dynamic Flat Detector features Xper Access which allows the flat detector to be positioned in either portrait or landscape imaging modes in 3 seconds.
- The variable source image distance between focus and Dynamic Flat Detector input screen is motorized from 86.5 to 123 cm.
- The stand features BodyGuard a capacitive sensing collision avoidance system for patient protection.

- **Maquet Magnus Interface**
- The Allura FD20 OR contains an interface to the Magnus (MAQUET) Operating table system (fixed column). The integration of the Magnus (MAQUET) surgery table includes support of:
- Safety:
  - Integrated Emergency Stop; all motorized movements (including table), are stopped when the Allura Xper emergency stop button is pressed
  - Integrated Collision detection, all motorized movements (including table), are slowed down or stopped when Bodyguard detects the patient
- Workflow:
  - Easy patient positioning with the basic table functions via Xper Geometry module and Magnus (MAQUET) UI controls; table height, tilt, cradle, longitudinal/lateral movement and reset geo.
  - Synchronized patient orientation setting between Magnus (MAQUET) and Allura Xper
- Advanced Functionality:
  - Iso-centric tilt features a tilt movement of the table top while keeping the point of rotation fixed in the iso-center of the imaging system.
  - Syncra-tilt synchronizes the stand orientation with the iso-centric tilt movement keeping the view perpendicular to the table top surface.

Accessories

100247 Allura Xper FD20 OR Table			
Line #	**Part #**	**Description**	**Qty**

- One Table-mounted Radiation Shield
- One anti-fatigue mat with Philips logo

X-ray Generation

The Allura Xper FD20 comprises an integrated dedicated X-ray system, micro-processor controlled Certeray generator based on high frequency converter technique. The user interface control of this X-ray Generator is incorporated in the Xper module, Xper Desktop Viewing Console, and the Xper on-screen displays.

The Certeray generator comprises:

- X-ray generator: 100 kW
- Voltage range: 40 - 125 kV
- Program selection:
  - Pulsed X-ray up to 3.75 , 7.5 , 15 , 30, frames/s for digital dynamic exposures
  - Pulsed X-ray for pulsed fluoroscopy (3.75, 7.5, 15, 25, 30 frames/s).
  - Minimum exposure time of 1ms.
  - ECG triggered acquisition: allows acquiring one exposure for each QRS peak with selectable delay time
  - Automatic kV and mA control for optimal image quality prior to run to save dose
  - Optimal X-ray tube load incorporated in the Certeray generator
- An X-ray collimator with single semi-transparent wedged filter with manual and automatic positioning.
- SpectraBeam filtering of low energy radiation to optimize image quality and dose efficiency with the MRC-GS 0508 X-ray tube.
- Xper Beam Shaping, which means that, both shutters and wedges can be positioned on the Last Image Hold without the need for X-ray radiation.

Fluoroscopy

- Three programmable fluoroscopy modes
  - Each mode can be set to different composition of dose rate, pulse speed, filter setting, and image processing (noise reduction, adaptive contour enhancement, and adaptive harmonization).
- Roadmap Pro
  - Roadmap Pro can be selected from the Xper imaging module and/or Xper module.
  - A vessel map is created and superimposed with (un)subtracted live fluoroscopy. Acquisition runs can be done during Roadmap without losing the vessel map. Roadmap Pro features Smart Settings in special clinical modes that are optimized to visualize special materials such as coils and glue. Live processing of the vessel map, the device map and the landmark map can be done on the Xper Module. Xres for vascular procedures is standard part of Roadmap Pro.
    - **Disclaimer:** AMC only corrects movement artifacts in two dimensions. Three dimensional movements such as swallowing or rotation of the head cannot be corrected.
  - In Roadmap Pro R2 "Automatic Motion Compensation" (AMC) is added to the roadmap functionality. During roadmap, small movements of the patient can lead to subtraction

artifacts. These artifacts might conceal important clinical information. "Automatic Motion Compensation" compensates for rigid, uniform (skeletal/table) translations and is therefore very effective in interventional (neurology) applications where subtraction imaging is applied.
  - Disclaimer: AMC only corrects movement artifacts in 2 dimensions. 3 dimensional movements like swallowing or rotation of the head cannot be corrected.
- Xper Fluoro Storage, a grab function allows storage and archiving of both a fluoro image and the last 20 seconds of Fluoroscopy, called Xper Fluoro Storage. These fluoro images or fluoro runs can be archived as a regular exposure run.
- Xres is a multi-resolution spatial temporal noise reduction and edge enhancement filter for interventional applications. Xres exploits the full benefits of dynamic digital flat detector imaging to enhance sharpness and contrast and has been designed to reduce noise in fluoroscopy and exposure runs. The settings for Xres Cardio can be customized to optimize image quality. Xres is Philips unique image processing algorithm developed at Philips Research for medical applications.

X-ray tube

The Allura Xper FD20 has the Maximus ROTALIX Ceramic grid switch tube assembly MRC 200 GS 0407 integrated in the C-arc. This MRC tube has an anode heat storage capacity of 2.4 MHU and 0.4/0.7 mm. nominal focal spot values. The tube has a maximal loading of 30 and 67 kW.

Dynamic pulsed fluoroscopy uses grid switching technology to eliminate soft radiation and improve image quality. SpectraBeam allows for filtration of the x-ray beam with (a combination of) 0.2, 0.5 or 1 mm CU-equivalent filters.

Tube housing ROT-GS 1004 is for oil-cooling and has a build-in thermal safety switch. A rotor control unit is build-in for continuous rotation of the anode disk. The heat exchanger CU 3101 is for direct and continuous forced cooling with oil.

IMAGE DETECTION

The Allura Xper FD20 comprises the following image detection chain:

- A 30 cm by 40 cm FD20 Dynamic Flat Detector with eight imaging modes.
  - 30 x 38, 30 x 30, 26 x 26, 22 x 22, 19 x 19, 16 x 16, 13.5 x 13.5, and 11 x 11 cm
- The digital output of the FD20 flat detector is 2k*2.5k image matrix at 16 bits depth for the largest mode
- The flat detector subsystem features Xper Access, the detector can be rotated over 90 degrees, it moves from portrait to landscape back & forth
- DQE (Detective Quantum Efficiency) >77%
- The pixel pitch: 154 x 154 microns

Viewing

The Allura Xper FD20 comprises the following components in order to display the clinical images in the control and examination room:

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Line #	Part #	Description	Qty

Displays

Examination Room

Two 19-inch monochrome LCD monitors designed for medical applications. The first display is used for viewing live images. The second display is the reference monitor.

- 19-inch monochrome TFT-LCD display with a 160 degree viewing angle.
- Native format 1280x1024 SXGA
- 10-bit gray-scale resolution with gray-scale correction

These monitors are not delivered when FlexVision XL, EP Cockpit or EP Cockpit XL is selected.

Unless otherwise stated, with FlexMove an integration kit is supplied for a third party Monitor Ceiling Suspension (MCS) containing crucial parts for operating the equipment.

Two medical monochrome LCD monitors are included for the exam room. One monitor is used for viewing of live images. The second monitor serves as the first reference display. Reference images or runs are controlled by infra-red remote-control Xper Viewpad.

- Of the two medical monochrome LCD monitors included in the MCS, one is used for viewing of live images and the other serves as the first reference display. Reference images or runs are controlled by infra-red remote-control Xper ViewPad.
- The On-Screen Display provides status information on stand rotation, angulation, display of system messages, X-ray tube load status, selected fluoroscopy mode, selected detector Field of View, and both the rate and accumulation of the dose area product and skin dose. For cardiac applications, the system also monitors and displays body zone specific Air Kerma data (10 zones).

Control Room

One 19-inch color LCD monitor used as a data monitor.

- 19-inch color TFT-LCD display
- Native format 1280x1024 SXGA

One 19-inch monochrome LCD monitor (Xper review monitor) designed for medical applications.

- 19-inch monochrome TFT-LCD display
- Native format 1280x1024 SXGA
- 10-bit gray-scale resolution with gray-scale correction

These control room monitors are not delivered when EP Cockpit or EP Cockpit XL is selected.

The Graphical User Interface on the monochrome monitor has the following features and functions:

- Step through file, run, or images
- File, and run overview
- Contrast, brightness, and edge enhancement settings
- Flagging of runs or images for transfer
- Applying text annotation in images
- Optional DICOM printing
- Executing Quantitative Analysis Packages if available
- Subtraction functionality
- Zoom/pan functionality
- Electronic shutters
- Video invert
- View trace, stacking of images
- Landmarking

Acquisition

The acquisition segment coordinates the parameters for automatic exposure control. The program is selected via the Xper module or Xper Desktop Console.

Exposure techniques:

- Serial imaging for DA and DSA with automatic exposure setting
- Single shot mode
- Acquisition frame rates: 0.5 to 6 images/s at 2048 x 2048, 12-bit matrix

The Allura Xper FD20 offers a storage capacity of:

- 50,000 images at matrix size of 1024 x 1024
- 12,500 images at matrix size of 2048 x 2048
- Maximum number of examinations is 999, with no limit to the maximum number of images per examination

USER INTERFACE

Xper is comprised of three elements: 1) Xper Settings, which customizes the system to each user preferred settings. 2) Xper User Interface 3) Xper Integration, which makes advanced integration functionality available such as DICOM Query / Retrieve, background archiving, and Xper Fluoro Storage.

The Xper User Interface uses User Interface modules in the Examination Room with On-Screen Display.

The On-Screen Display is positioned on the left side of the reference monitor. The following system information is displayed

- X-ray indicator and X-ray tube temperature condition
- Gantry position in rotation, angulation, and Source Image Distance
- Detector field size display
- General System messages
- Selected Frame speed
- Fluoroscopy mode
- Integrated fluoroscopy time
- Skin Dose and Dose Area Product
- Stopwatch

The Xper ViewPad contains the preprogrammed function settings. The system is provides with two Xper Viewpads. The following functions are provided:

- Run and image selection
- File and run cycle
- File overview
- Store to Reference image file
- Copy image to photo file
- Digital (fixed) zoom and panning
- Recall reference images
- Laser pointer, intended to point at regions of interest on the imaging monitors
  - LED indication of laser pointer on/off and battery low
- Subtraction on/off
- Remasking
- Landmarking

Remote Intercom

The separate intercom which is connected independently from the system that allows separate placement of the intercom at the preferred working position in the control room and examination room.

Table Side Modules

Two Xper Modules are provided for use. The first Xper Module is positioned at the Xper pedestal where the pedestal can be freely positioned at all sides of the patient table. The Second Xper Module (NCVA778) is located in the control room. These modules use a touch screen, which can be operated when draped with sterile covers. The Xper Module contains the following functionality:

- Acquisition settings
- Selection of Xper Setting allows the user to set frame rates and X-ray generation settings applicable for the type of the preferred intervention
- Image Processing

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Line #	Part #	Description	Qty

The Xper Geometry module is positioned at the Xper pedestal where the pedestal can be freely positioned at all sides of the patient table, while keeping the button operation intuitive. The Xper Geometry module provides the following functionality:

- Tabletop float and table height position
- Source Image Distance selection
- Longitudinal movement of the Gantry along the ceiling
- Gantry rotation in an axis perpendicular to the ceiling
- Store and recall of two scratch gantry positions including SID
- Emergency stop button

The Xper Imaging is positioned at the Xper pedestal where the pedestal can be freely positioned at all sides of the patient table, while keeping the button operation intuitive. The Xper Imaging module provides the following functionality:

- Fluoroscopy Flavor selection defined per Xper Setting
- Shutters and Wedge positioning
- Xper Fluoro Storage and Grab
- Selection of the Detector field size
- Shutter positioning
- Reset of the fluoroscopy buzzer

Xper pedestal

The Xper pedestal is the flexible work spot for operating the system in the examination room. The pedestal is provided with a Xper Geometry and Imaging Module and has the possibility to hold the X-ray footswitch. An Xper module is mounted on the pedestal to create a work spot with full system control. The Xper pedestal is connected to the system by means of a wall connection box and can be positioned freely around the patient table with a cable length of 8 meter. The pedestal has been designed with stability and eases of use in mind and can be stowed away near the wall connection box when not used.

Pan Handle (NCVA081)

- The Pan Handle is an extension of the control facility for floating movements of the tabletop.

Control Room

The control room comprises a Xper Review Module, Xper Desktop Module, a keyboard, and a mouse. The Xper Review Module offers the basic functions for review. The Xper Review Module contains the following functionality:

- Power on/off
- Tagarno wheel to control the review of a patient file
- File and run cycle
- Contrast, Brightness, and Edge enhancement settings
- File, Run, Image stepping and run and file overview
- Delete run
- Image invert and digital zoom

- Reset fluoroscopy timer and enable/disable X-ray

System information is displayed on the bottom of the data monitor:

- Stopwatch and Time
- System guidance information
- Dose Area Product (DAP) and Skin Dose, and accumulative dose
- Frame speed settings, fluoroscopy mode, and accumulated fluoroscopy time
- Exposure and fluoroscopy settings as Voltage (kV), Current (mA) and pulse time (ms)
- Geometry information as rotation, angulation, and SID

Scheduling

The patients can be listed and selected per date, physician, and intervention type. Previous DICOM patient studies can be uploaded with the DICOM Query Retrieve function in the Allura system.

Patient management protocols are flexible and allow for multiple studies to be selected under one patient identification number. This means that new studies can be appended to an earlier patient file. Furthermore, each study can contain multiple examinations to allow for split administrative purposes. Each examination contains multiple files, like acquisition file, reference file, and QA results file.

Preparation

The preparation page provides the information of the room and patient preparation of each individual physician. The preparation page is customizable per Xper Setting and allows each physician to provide his own room protocols. This preparation page makes hard copies of the protocol instructions redundant.

Acquisition

The acquisition page contains information on the current selected patient.

Review

The review page allows for reviewing of patients:

- Previous examination cases
- Review of other DICOM XA or DICOM SC studies

Vascular Quantification Software Package

Functions:
- vessel diameter / stenotic index
- automated vessel analysis
- calibration routines

In addition the package allows manual measurements of line lengths (absolute and ratio's) and angulations. Multiple measurements in one image are possible.

RIS/CIS DICOM Interface

This package allows communication of the Allura Xper system with a local information system (CIS or RIS). The interface uses the DICOM Worklist Management (DICOM WLM) and Modality Performed Procedure Step (DICOM MPPS) standards.

If a hospital has an Allura Xper system and an information system it can receive patient and examination request information from the information system and report examination results in order to:

-Eliminate the need for retyping patient information on the Allura Xper
-Prevent errors in typing patient names and registration numbers (ensuring consistency with IS information to prevent problems in archive clusters auto-search for a name in case of later retrieval)
-Inform the IS about the acquired images and radiation dose

Upon request from the Allura Xper system the complete worklist with all relevant patient and examination data is returned from the IS to the Allura Xper system. For each patient the following information will be shown on the Allura Xper after it has been retrieved from the IS:

Patient Identification:

- Patient name
- Patient ID
- Birth date
- Sex

Examination/Request Information:
- Accession number
- Scheduled procedure step start time
- Scheduled performing physician's name

It is possible at all times to enter patient demographics information manually within the Allura Xper system in case of an emergency or in case the local Information System connection is down.

On request of the clinical user the Allura Xper will report the following information about the selected patient to the IS:
Patient Identification:
- Patient name
- Patient ID
- Birth date

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Line #	**Part #**	**Description**	**Qty**

- Sex

Examination/Request Information:

- Accession number
- Performed procedure step status start/end date and time
- Performing physician's name
- Referenced image sequence

Radiation dose:

- Total time of fluoroscopy
- Accumulated fluoroscopy dose
- Accumulated exposure dose
- Total dose
- Total number of exposures
- Total number of frames

Further detailed information can be found in the Allura Xper DICOM Conformance Statement.

The interface requires an EasyLink (hardware and software) if the IS is not compliant with DICOM Work List Management and Modality Performed Procedure Step.

Radiation Dose Structured Report

Collection of dose relevant parameters and settings and export to a DICOM database (e.g. PACS, RIS), according IEC60601-2-43, 2nd Edition.

The reported data can be used for, for example:

- Quality improvement: evaluating trends in X-ray dose performance per facility, system and operator.
- RDSR enables analysis of average dose levels & variance for routinely performed exams and procedures.
- Typical system usage can be extracted from the data.

Secondary Capture Dose Report

- The Secondary Capture Dose Report function allows the user to save & transfer, manually or automatically, a patient Dose Report to PACS in DICOM secondary capture format.
- The dose report will be stored in the related patient image folder.

Archive

Continuous Autopush (NCVA090)

Continuous Autopush is an archive accelerator, which ensures that background archiving continues with minimal disruptions.

Clinical studies can be archived to a CD or a PACS. The archive process can be completely automated and customized with Xper Settings. Parameters like multiple destinations, archive formats can be selected to the individual needs and wishes for programming under the Xper Settings,

The Xper DICOM Image Interface enables the export of clinical images to PACS. The export formats are based on DICOM 3.0 protocols. The system exports clinical studies in Cardiac DICOM XA Multi-Frame or DICOM Secondary Capture formats.

- The export format is configurable in 512x512, 1024x1024 2048 x 2048 (unprocessed) matrix.
- The examination can be sent to multiple destinations for archiving and reviewing purposes.
- The Xper DICOM Image Interface provides DICOM Storage and DICOM Storage Commitment Services.
- The DICOM Query/Retrieve function allows older DICOM XA MF and DICOM SC studies to be uploaded in the system. Furthermore, additional information can be appended to a study, while keeping the patient identification the same.

Remote Service

Access to the system from a Remote location is possible via network or modem connection. Remote access to a system can shorten the time needed for e.g. changing system settings or problem diagnosis.

Clinical Education Program for the Allura Xper System

Essentials OffSite Education: Philips will provide up to two (2) Cardiovascular Technologists, Registered Technologists Registered Nurses, or other system operator as selected by customer, with in-depth didactic, tutorial, and hands-on training covering basic functionality and work-flow of the cardiovascular imaging system. In order to provide trainees with the ability to apply all fundamental functioning on their system, and to achieve maximum effectiveness, this class should be attended no earlier than two weeks prior to system installation.

In the event that an EP Navigator workstation has also been ordered, the offsite training course will be tailored to focus on the electrophysiology functionality of the FD system and the EPN workstation.

In the event that your main FD system will be dedicated to Cardiac applications your offsite training course will be tailored to focus on the Cardiac functionality.

This twenty-eight (28) hour class is located in Cleveland, Ohio, and is scheduled based on your equipment configuration and availability. Due to program updates, the number of class hours is subject to change without notice. Customer will be notified of current, total class hours at the time of registration. This class is a prerequisite to your equipment handover OnSite Education. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. **Travel and lodging are not included, but may be purchased through Philips. It is highly recommended that 989801292102 (CV Full Travel Pkg OffSite) is purchased with all OffSite courses.**

Handover OnSite Education: Philips Education Specialists will provide twenty-eight (28) hours of education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. Students should attend all 28 hours, and must include the two

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Line #	Part #	Description	Qty

OffSite education attendees. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. Note: Site must be patient-ready. Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. **It is highly recommended for systems that are fully loaded or for customers with a large number of staff members to also purchase 989801292099 (CV Add OnSite Clin Educ 24h).**

Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref #106107-110915

Clinical Education Program for FlexMove C-Arm

FlexMove C-Arm OnSite Education: Philips Education Specialists will provide twenty -four (24) hours of pre-training applications for up to (8) students selected by customer, including technologists from night/weekend shifts if necessary. This training will be coordinated to provide instruction on the operation of the FlexMove C-Arm prior to the Go Live handover date of the entire Allura Imaging System. **In the event that a Maquet OR table** with 24 hours of pre training has also been purchased this FlexMove 24 hour training will be used as a post handover follow up session. No CEU credits will be available for this session. Please refer to guidelines for more information. Note: The equipment must be entirely operational. Philips personnel are not responsible for actual patient contact or operation of the equipment during the education sessions except to demonstrate proper equipment operation.

Education expires one (1) year from equipment installation date (or purchase date if sold separately) . Ref #699-20110915

2	**NNAE159	30Fr/sec Extension	1	

Frame Rate Extension increases the system acquisition speed for cardiac applications that require high speed imaging. The frame rate extension increases the acquisition speed to 15fps and 30fps with a 1024x1024 matrix.

3	**NNAE853	FlexVision_XL 8 Input Package	1	

The FlexVision XL8 input package provides eight isolated wall connection boxes.

Isolated Wall Connection Box

This Isolated Wall connection Box facilitates connection of the video source via standard DVI cable/connector and lossless transfer of the video signal over the approximate 30 m cable distance. It can be mounted in the exam room or in the control room, depending on the location of the video source.

The quantity of the VWCB's has to be calculated as follows:

For each video signal to FlexVision XL on Vascular System: 8 VWCB

Note:

No VWCB is required in case a video signal is connected directly to a dedicated LCD from the following sources:

100247 Allura Xper FD20 OR Table

Line #	Part #	Description	Qty

1) Xper Live/ref Slaving

2) Interventional HW (XtraVision), ViewForum, Xcelera (only if workstations are powered by Allura Xper)

3)Xper IM

4 **NCVC490 Maquet ORT integration kit 1

The ORT system contains an interface to the Magnus (MAQUET) operating table system (fixed column).
The integration of the Magnus (MAQUET) surgery table includes support of:
- Safety: Integrated Emergency Stop; all motorized movements (including table), are stopped when the Allura Xper/AlluraClarity emergency stop button is pressed; Integrated Collision detection, all motorized movements (including table), are slowed down or stopped when Bodyguard detects the patient.
- Workflow: Easy patient positioning with the basic table functions via Xper Geometry module and Magnus (MAQUET) UI controls; table height, tilt, cradle, longitudinal/lateral movement and reset geo. Synchronized patient orientation setting between Magnus (MAQUET) and Allura Xper/AlluraClarity.
- Advanced Functionality: Iso-centric tilt features a tilt movement of the table top while keeping the point of rotation fixed in the iso-center of the
imaging system. Syncra-tilt synchronizes the stand orientation with the iso-centric tilt movement keeping the view perpendicular to the table top surface.
On the Xper User Interface (On-Screen Display) in the Examination room, OR table specific information is displayed:
- Table height
- Table top tilt and cradle angle (if applicable)

The Xper Module contains the following OR table functionality:
- Automatic Position Control option for stand and table positioning

The Xper Geometry Module provides the following OR table functionality:
- Table top float
- Table height position
- Table tilt angle (if applicable)
- Geometry reset button, which resets stand and table to a factory-default starting position
- Unlocking button for table pivot function (if option is installed)
- Table tilt and cradle controls (if option is installed)

5 **NCVA801 Table APC 1

The Automatic Position Controller (APC) for the table provides two modes of operation:

- Auto positioning. The tabletop position and table height will be adjusted automatically to the pre-defined default point of interest. This to save time and x-ray dose at the start of an exam or for setting up the system for rotation scans.
- Store/recall of a position of the table top. This includes the height-, longitudinal- and lateral position of the table top.

6 **NCVA695 FD Rotational Angio 1

100247 Allura Xper FD20 OR Table

Line #	Part #	Description	Qty

Rotational angiograpy provides real-time 3D impressions of complex vasculature and coronary artery tree. It acquires multiple projections with just one contrast injection via a fast rotational scan of the region of interest.

Rotational Angiograpy can be used during screening procedures to quickly determine the optimal projection for the study as the angle (rotation/angulation) of the projection is indicated on each image.

Compared with traditional angiography, Rotational Angiography can save considerable time, dose and contrast, while providing image detail required for diagnostic and therapeutic decisions.

A rotational scan is possible both with the Allura Xper systems in the side position (ceiling mounted systems) and in the head position, providing the flexibility to perform procedures virtually from head to toe.

C-arm in side position:

- Max. rotation Speed: 30 degrees/s
- Max. rotation Angle: 180 degrees

C-arm in head position:

- Max. rotation Speed: 55 degrees/s
- Max. rotation Angle: 305 degrees

Max. Frame speeds are given by the framespeed specifications of the system configuration.

The speed and range of rotation are the highest available (see table). The very high speed allows using less contrast, whereas the very wide rotation range provides a complete evaluation of the anatomy.

A contrast run can be followed up with a mask run, to allow image/run subtraction.

The stand is designed for a very high mechanical stability. It offers precise positioning and high reproducibility, assuring you of high quality images and excellent subtraction studies.

Operation of Rotational Angiograpy is extremely easy. The procedure is selected, set up and executed virtually in a matter of seconds, supporting the highest patient throughput.
A set of dedicated acquisition programs is available on the Xper Module and can be selected at the touch of a button. The rotation end- and start-positions are easily selected. The procedure is controlled from the exposure hand- or footswitch.

Line #	Part #	Description	Qty
7	**NCVA694	Subtracted Bolus Chase	1

For visualization of vessel structures when the blood flow is difficult to estimate, in particular in the lower peripherals.

Bolus Chase solves the problem of cumbersome step movements, the mismatch between blood flow and selected program, and lack of real-time image information.

100247 Allura Xper FD20 OR Table

Line #	Part #	Description	Qty

During digital acquisition in non-subtracted mode with uninterrupted real-time image display, the contrast bolus is followed (chased) interactively by a motorized table scan movement using a hand-hold speedcontroller to adapt the speed of the table scan to the contrast flow.The framespeed can be adapted as well.

The bolus run is followed with a mask run while using the same speedcurve and framespeed as generated during the bolus run. Viewing is possible in the subtracted and non-subtracted mode. If subtracted viewing is not required, the mask run can be skipped.

Subtracted Bolus Chase gives fast, accurate results for increased patient throughput and improved patient management. Automated exposure control and precise speed control assure a high quality images and excellent subtraction studies.

Comprising:

- automatic exposure control
- tabletop motordrive and hand-held speed controller (tableside)
- technique selection using Xper module, available both tableside and in control room (Xper FD20, FD20/10)

8 ****NCVA693** **FD Dual Fluoro** **1**

Dual Fluoro for Flat detector systems

The Dual Fluoroscopy mode allows digitally processed fluoroscopy in parallel with trace subtract fluoroscopy, providing a non subtracted reference fluoro image for complex interventions.

This option provides an additional fluoro channel in parallel to the default fluoro channel. The Dual fluoroscopy mode is selected via the Xper module.
The trace subtracted fluoro image will be displayed on the exam monitor, the non-subtracted fluoro image is displayed on the reference monitor.
In Dual Floro mode, The fluoroscopy image on the exam montitor can be zoomed digitally with a factor 2, providing a larger view of the region of interest for complex interventions. The fluoro zoom function is controlled via the Xper module.

9 ****NCVA672** **FD SmartMask** **1**

SmartMask simplifies roadmapping procedures by overlaying a selected reference image with fluoroscopy on the live monitor in the exam room.
The reference image can be faded in/out with variable intensity, controlled from tableside.
SmartMask uses the reference image displayed on the reference monitor.
Any previously acquired image can be used as reference.

SmartMask facilitates pre- and post- intervention comparisons to assess treatment results

10 ****NCVA101** **Peripheral X-ray Filter** **1**

Set of flexible x-ray filters to provide an uniform density in angiographic examinations of the lower peripheral area.
Comprising:
· one central filter, at the top edge provided with sizing markers at every 5 cm, length : 1 m
· two side filters, length: 1 m

11 ****NCVC319** **HeartNavigator R2** **1**

100247 Allura Xper FD20 OR Table

Line #	Part #	Description	Qty

Performing a structural heart procedure can be a breath-taking and tense intervention. HeartNavigator Release 2 provides support in planning of the procedure and additional live image guidance during the procedure. Previously acquired DICOM cardiac CT-datasets can be used as input. The CT-dataset can be presented in 3D and overlaid with the live-fluoroscopy to provide 3D real time insight during the procedure.

Planning:
DICOM Cardiac CT dataset can be used for the determination of the optimal intervention strategy. HeartNavigator Rel. 2 is able to automatically segment anatomical structures, landmarks and planes out of DICOM cardiac CT-datasets. It provides fully automated diameter and distance measurements of anatomical structures around the aortic root for TAVI/TAVR procedures. Furthermore, the automatically generated anatomical views can be used as reference views during the procedure. Additional reference view planes for the X-ray device can be stored.

Different tools are available to help the user with the planning:

- Different anatomical visualization tools can be selected. The calcification visualization option gives insight in the calcification distribution in the ascending aorta, aortic valve and left ventricle.
- Different anatomical landmark points are available to help the user to better understand the orientation and positioning of devices.
- Different sizes of virtual devices which can be selected and projected on the CT data to give a reference on how the device would fit the patient.

Image Acquisition Procedure Execution:
During live image guidance HeartNavigator can be fully operated from table side using the XperModule. The user can overlay the acquired images on the 3D reconstruction of HeartNavigator.
The bidirectional link between the X-ray system and HeartNavigator allows the user to select the optimal stand position for the procedure in two ways. 3D Automatic Position Control allows the gantry to automatically move to the projection of the reference views that are shown on the HeartNavigator monitor. 3D Follow C-arc allows the overlay to remain in sync with the 2D projection, automatically adjusting the viewpoint as the gantry is repositioned. Table motion compensation (or L-arm tracking in case of FlexMove) makes sure that they overlay keeps following the table movement during table panning. Different visualization options are available like 3D volume and vessel outline to select as overlay.

Clinical Education Program for iXR Heart Navigator:

iXR Heart Navigator OnSite Education: Philips Education specialist will provide sixteen (16) hours of education for up to (4) students selected by the customer . The Physicians performing the procedures are required to be part of the training session. CEU credits may be available for each participant that meet the guidelines provided by Philips. Please refer to guidelines for more information. Note: Site must be patient ready. Philips personnel are not responsible for actual patient contact or operation of the equipment during the educations sessions except to demonstrate proper equipment operation.

100247 Allura Xper FD20 OR Table

Line #	Part #	Description	Qty

iXR Heart Navigator OnSite Live Case Follow Up Education: Philips Education Specialist will provide twenty -four (24) hours of education for Physicians and staff for live case use of the Heart Navigator software. This will be a follow up visit to the initial training of the Heart Navigator software. It is required that Live Valve implantation studies be performed during this education session. No CEU credits will be available for this session. Please refer to guidelines for more information. Note: Site must be patient ready. Philips personnel are not responsible for actual patient contact or operation of the equipment during the educations sessions except to demonstrate proper equipment operation.

Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref # 694698-20110915

Physician Taught HeartNavigator Workshop

This physician taught and hands-on workshop provides instruction and practice using HeartNavigator. It also covers the technical aspects and benefits of using overlay on fluoroscopy for live guidance purposes.

You will get hours of hands-on practice, working with your own workstation in a small group setting and you will discuss best practices with other participants to gain new insights and avoid common pitfalls.

The 12 hour/1.5 day workshop is located at The Center of Advanced Medical Learning and Simulation (CAMLS) in Tampa, Florida. It is in conjunction with Tampa General Hospital.

This package includes tuition for one clinician and one X-ray tech to attend this workshop. Travel packages and additional attendee packages can be purchased separately.

12	**NCVB878	Interventional Tools Hardware	1

The Interventional hardware is the hardware for the interventional tools and enables import and viewing of DICOM compatible data from other imaging modalities.

The processing platform provides two visual outputs, one for the control room and one for the examination room.

An available color LCD display, or an EP cockpit, EP cockpit XL or FlexVision XL display solution is required for the examination room.

The Interventional Hardware comprises at least:
- Computer Workstation
- CR 19" display • 16 GB memory
- 2 TB disk for the operating system, application software and application data
- Internal CD-Rom / DVD writer
- Mouse tablet to interact with all the interventional tools at the table side.

Conditionally:
FD Calibration Tool Kit for 3D-RA and/or XperCT.

100247 Allura Xper FD20 OR Table

Line #	Part #	Description	Qty
13	**NCVA590	**Real time image link**	1

Real Time digital image link to an off-line Allura Interventional Hardware station. This applies on the applications 3D-RA, StentBoost and 3D-CA on the Interventional Hardware. This dedicated digital link sends raw or processed image data (depending on the application) real time during monoplane exposures to the connected Interventional Hardware station, to allow instant results of the applicable reconstruction after the exposure run.

In biplane systems, this digital link is available for the frontal channel only.

14	**NCVA116	**3D RA Control for Xper Module**	1

Table Side Module functionality for Allura Xper FD20 used with Integris 3D-RA Release 4.2.

For further improvement of interventional procedures efficiency the following workflow enhancers are made available in the examination room: With the Xper touchscreen module the physician has all 3D functionality needed at tableside. Functionality like rotating panning zooming AVA Virtual stinting 3 and 3D Follow C-arc can be perfomed. No need for the Physician to leave the examination room. 3D Automatic Position Control (3D-APC); when the optimal working position has been chosen via the Integris 3D-RA interventional tool the C-arc will automatically steer to this position.3D Follow C-arc: When the position of the C-arc (not using any X-ray) is changed the 3D volume will automatically follow the position of the C-arc. This means the position of the C-arc (and therefore the 2D projection) and the 3D volume are always aligned.

15	**NCVB775	**FlexV XL xperHD for 3rd p. MCS**	1

FlexVision XL with XperHD

FlexVision XL for Allura Xper FD & AlluraClarity systems with large 58-inch high resolution color LCD in the Exam Room. FlexVision XL is an integrated viewing solution designed to give you full control over your viewing environment.

The FlexVision XL provides the ability to:

- Display 2 to 8 screens simultaneously from up to 16 sources (incl. third party systems) on the Philips 58-inch color LCD in the Exam Room.
- Resize and/or enlarge information at any stage during the case.
- Select and customize viewing lay-outs of the Philips 58-inch color LCD via the Xper table-side module
  XperHD on FlexVision XL brings High Definition viewing for clinical images. Native resolution of FD20 can be displayed. Excellent sharp and crisp clinical images can be displayed at full size without digital zoom.
  Xper HD brings:
  - High Definition imaging
    – Sharp images at full size without zoom
  - High Definition display at native resolution
    – Up to 2k*2k image display fully integrated
  - High Definition for the ultimate detail
    – Enhanced small vessel visualization
  - Overview connected equipment (incl. third party systems) from a single location.

The FlexVision XL consists of:

- OmniSwitch

100247 Allura Xper FD20 OR Table

Line #	Part #	Description	Qty

- OmniSwitch allows the user to direct and switch the video output of all connected medical equipment to specific sub windows of the Philips 58-inch color LCD in the Exam Room.
- OmniSwitch is a 16 channel video-switch operated from the Xper tableside module. 16 channels are available for a mix of up to 7 internal and up to 9 external inputs.
- OmniSwitch supports a wide variety of display formats (up to 1600x1200).
- External inputs are connected to OmniSwitch via Wall Connection box(es).

- Medical grade, high resolution color LCD in the Exam Room
  - This display supports the image quality requirements for monochrome X-ray images as well as color images and replaces all displays normally delivered with an Allura Xper FD system for the Exam Room.
  - Main characteristics are:
    - 58 inch, 8 Megapixel color LCD
    - Native resolution: 3840x2160
    - Brightness: Max: 450 Cd/m2 (typical) stabilized: 350 Cd/m2
    - Contrast ratio: 1200:1 (typical)
    - Wide viewing angle (approx. 176 degrees)
    - Constant brightness stabilization control
    - Lookup tables for gray-scale, color and DICOM transfer function
    - Full protective screen
    - Ingress Protection: IP-21
- Large color LCD control (Xper Module)
  - Resize and/or enlarge information at any stage during the case via the Xper tableside module in the Exam or Control Room
  - Select viewing lay-outs via the Xper table-side module in the Exam Room
  - Create new layouts by matching inputs to desired locations on preset templates.
- Isolated Wall Connection Boxes
  - Up to 8 Isolated Wall Connection Boxes can be connected to FlexVision XL.
  - Through Isolated Wall Connection Boxes, 3rd party equipment can be connected to the FlexVision Omniswitch.
- Snapshot
  o The snapshot function allows the user to store/save a screen-capture of any image on the 58" display as a DICOM Secondary Capture image to a connected PACS. The snapshot-all function allows the user to store/save a screen-capture for each displayed image in the Exam Room Room as separate DICOM Secondary Capture images. The FlexVision XL can be mounted on a 3 party MCS. This gives the possibility to be more flexible in the positioning of the FlexVision XL in the exam room. This is often requested in Hybrid OR's

16	**980406041009	**Rad Shield w/ Arm (Contoured) 61X76**	2

Contoured Rad Shield with Arm rest. 61X76

17	**989801220158	**Mark 7 Arterion, Table Mount**	1

The Mark 7 Arterion Injection System is the latest in MEDRAD's "Mark" series of angiographic injectors. Compared to earlier systems, the Mark 7 Arterion injector head is lighter and easier to use so you can focus more on the patient.
The clear and intuitive user interface guides you through proper set-up, and highlights the information you need to perform safe procedures.
Unique to the market, the front load system simplifies set-up and makes for a cleaner tear down.
The clear syringe provides a higher level of confidence that you are ready to inject.

Line #	Part #	Description	Qty

Made from a clear material, the Mark 7 Arterion syringe (Catalog ART 700 SYR) allows you to easily view the inside of the syringe for smoother purging of air. And MEDRAD's famous fluid dots are still there to help-round for fluid, oval for air.
The table mount injector solution ensures the contrast injector is conveniently placed and always available when it is needed. It provides a clean workspace without occupying valuable floor space.
System includes:

- Table Mount
- display control panel
- 6 ft. coiled hand switch
- operation manual (CD)
- 10 ft. head cable
- syringe heat maintainer
- imaging system interface cable for the Allura / Allura Xper
- consumables starters kit

For the MEDRAD Mark7 Injector system Philips is only the distributor. MEDRAD provides the service as well as the application support of both versions unless stated differently in the Philips Service Agreement

System Specifications:

- Flow Rate 0.1-45.0 ml/s in 0.1 ml increments
- 0.1-59.9 ml/m in 0.1 ml increments
- Volume 1-150 ml in 1 ml increments
- Pressure Limit 100-1200 psi in 1 psi increments
- (150ml syringe) 689-8273 kPa in 1 kPa increments
- Rise Time 0.0-9.9 seconds in 0.1 increments
- Delay Time 0.0-99.9 seconds in 0.1 increments
- Fill Speed 1-20 ml/s
- Fill Volume 1-150 ml
- Syringe Size 150 ml
- Syringe Heat Maintainer 35 °C (95 °F) ± 5 °C (9 °F)
- Protocol Memory 40 Protocols
- Injection Memory History

18	****989801220273**	**Ceiling Track w/Column & Handle Ext**	**1**

Mavig 2.5m Ceiling Track with Ceiling trolley, 360 degree column, and brake handle extension.

19	****989801220281**	**25 kVA Fluoro only UPS - UPC**	**1**

25 kVA Fluoroscopy Only Solution, Release 8.2 Ready.
This system includes the following components:

25 kVA UPS

- 480v AC 3 phase input; 480v AC 3 phase output
- Fully rated Static Bypass Switch
- Input Isolation Transformer; Output AutoTransformer
- Dimensions: 36.3D x 20"W x 59.8H"

100247 Allura Xper FD20 OR Table

Line #	Part #	Description	Qty

- Weight: 998 lbs (approximate).

Universal Power Controller (UPC)

- Combines the Battery Cabinet and Universal Transfer Switch Functions.
- Provides 12.5 Minutes of runtime at full load on battery
- Provides all interconnections to fully integrate into CV Lab.
- All previous 480V system functionality retained from previous separate component design.
- All connections are via external terminal blocks, rear access.
- All breakers are externally accessible from front.
- Isolated compartments for Battery and Switch sections.
- Fully ETL tested and certified UL, cUL and CSA Compliant.
- Dimensions: 31.5"D x 17.2"W x 59.8"H
- Weight: 1020 lbs (approximate).

DC Power Supply

- Artesyn/Emerson Part Number 73610129
- Single Unit Included for Mono Plane Systems
- Dimensions: 13.9" L x 6" W x 3" H
- Weight: 40 lbs (approximate).

Wiring Harness

- Complete Harness connecting UPC and UPS to MA Cabinet, includes control and Auxiliary connections and wire sizes per schematics. 50ft UPC to MA and 15ft UPC to UPS.
- Shipping Dimensions: Approx 31"L x 28"W x 22"D
- Weight: 140 lbs (approximate).

R8.2.1 UPS Control Kit

- Knife Switch rated 100A at 600V
- 120V rated Aux Switch Contacts
- Wall Mounted NEMA Enclosure
- Dimensions: 20"Hx 15"W x 8"D
- Weight: 25lbs

Included in UPC:

- Contactor MC3

20	**Third Party Item**	**Hybrid OR Comps:lts,booms,dspys, vid int**	**1**

100247 Allura Xper FD20 OR Table			
Line #	**Part #**	**Description**	**Qty**
	Hybrid OR Components: (3)Lights,(5)booms,(5)displays, video integration		
21	**Third Party Item**	**Flexvision boom**	**1**
	Flexvision boom		
22	**Third Party Item**	**Maquet Table**	**1**
	Maquet Table		

100247 Allura Xper FD20 OR Table

NET PRICE $1,972,443.00

Buying Group: HEALTHTRUST PURCHASING GROUP Contract #: 500005

Addt'l Terms:

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

Price above does not include any applicable sales taxes.

The preliminary delivery request date for this equipment is:_____.

If you do not issue formal purchase orders indicate by initialing here_____.

Tax Status:

Taxable_____ Tax Exempt_____

If Exempt, please indicate the Exemption Certification Number:_____, and attach a copy of the certificate.

Delivery/Installation Address:

_____

_____

_____

Invoice Address:

_____

_____

_____

Contact Phone #:

_____

Contact Phone #:

_____

Purchaser approval as quoted:

_____

Date:

_____

Title:

_____

This quotation is signed and accepted by an authorized representative in acknowledgement of the system configuration, terms and conditions stated herein.

100247 Allura Xper FD20 OR Table

OPTIONS

SELECTION OF ANY OPTION WILL INCREASE THE CONTRACT PRICE BY THE AMOUNT SHOWN IN THE PRICE COLUMN. OPTIONAL EQUIPMENT PRICING VALID ONLY IF PURCHASED IN CONJUNCTION WITH EQUIPMENT QUOTED.

Line #	Part #	Description	Qty	Each	Price	Initial
1	**NCVB868	CX50 Video and UI coupling	1	$6,052.60	$6,052.60	_____

The CX50 Integrated Ultrasound feature has been designed to easily and efficiently integrate ultrasound into the interventional suite.

Patient data:
Allura Xper patient information automatically transfers to the CX50
X-Ray and ultrasound patient studies may be configured with unique or identical study IDs to easily store and locate studies in DICOM
Image display:
The CX50 video output displays on the exam room LCD monitor
Integrated controls:
The Allura Xper Tableside Module remotely controls specific ultrasound modes and functions, including:
Modes: 2D, Color Doppler, Color Power Angio (CPA), Clinical presets
Functions: Zoom, Focus, Depth, Gain, iSCAN one-button optimization, Freeze, Acquire, Caliper, Replay, 2D Sector Width, Color Region of Interest, Biopsy Angles
Mouse interaction: remotely control the CX50 at the tableside using a mouse and tablet

Line #	Part #	Description	Qty	Each	Price	Initial
2	**NCVC132	EchoNavigator R2	1	$148,702.10	$148,702.10	_____

Structural heart procedures often rely on X-ray imaging to visualize the devices, while simultaneously relying on TEE Echo imaging of soft tissue and anatomical structures. EchoNavigator is a real time imaging modality that supports structural heart procedures by combining both X-ray and echo in an interactive, intuitive and procedurally relevant way.

EchoNavigator is based on a real time, advanced imaging platform that combines the 3D TEE Echo and X-ray images. It provides two visual outputs (with 1920*1200 display resolution), one for the control room and one for the examination room. The visual output for the control room is connected to a dedicated color 24" wide screen LCD display and is part of the EchoNavigator solution. The visual output for the examination room shall be connected to a FlexVision XL display solution.

A mouse and mouse tablet (with table attachment) is included to operate the EchoNavigator functionality from the Allura Xper table side.

EchoNavigator includes an Interventional Echo Link. The Interventional Echo Link provides a high speed live 2D and 3D digital connection between the Echo unit and the EchoNavigator imaging platform.

Features EchoNavigator:

To facilitate the interpretation of Echo images, EchoNavigator allows for multiple user-defined live views of Echo data, showing relevant anatomical structures from different angles simultaneously in real time. The image orientation of the 'C-arm" view automatically synchronizes Echo images with the X-ray images. The Echo viewpoint is automatically adjusted as the gantry is repositioned (follow C-arc).

To further help the understanding of the Xray and Echo image relation, EchoNavigator projects the ultrasound field of view (Ultrasound cone) as an outline into the X-ray view.

Multiple markers can be placed on soft tissue anatomical structures in the Echo image and these markers automatically appear in the X-ray image to provide context and help guidance.

100247 Allura Xper FD20 OR Table

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Line #	Part #	Description	Qty	Each	Price	Initial

An elliptical shape, in addition to single point markers, can be selected as annotation to mark anatomical regions of interest.

A movie of the main display area can be recorded to capture interesting events and sequences during the intervention. Retrospective as well as prospective recordings are supported.

The EchoNavigator user interface is optimized for use from the table side. This allows the X-ray operator to interrogate the relevant anatomical structures in the Echo images supporting workflow and communications with the Echo operator.

EchoNavigator Requires:

• EchoNavigator compatible Echo system, probes, and licenses/software

• EchoNavigator compatible Allura system, hardware, and licenses/software

• FlexVision XL display solution

• The lab must have one free Allura Wall Connection Box in the exam room (to connect the Echo unit) and one free Allura Wall Connection Box in the control room (to connect the EchoNavigator system). In case no free Wall Connection Boxes are available, additional Wall Connection Boxes shall be ordered & installed or existing WCBs shall be re-assigned.

IXR EchoNavigator Imaging Systems OnSite Education

Philips Imaging Systems Clinical Education Specialist will provide eight (8) hours of education for up to four (4) students, selected by customer, including technologists from weekend/night shifts as necessary. CEU credits are not available for this portion of training. Please refer to guidelines for more information. Note: Site must be patient ready. Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation.

Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref #819-20121213

2 DAY USCE ENT L3D TEE w/travel

2 Day Purchased TEE University with Travel - A variety of Live 3D TEE University course offerings are available to meet your educational needs. Live 3D TEE provides cardiologists, anesthesiologists, and cardiac surgeons novel and exiting realistic views to aid in patient care. The 2 Day PUR TEE University Tuition includes both the tuition and the corjameresponding travel package.

Due to travel and scheduling requirements, a twenty-one (21) day notification of cancellation is required or training / education entitlements will be forfeited. Curriculum is subject to change without notice.

100247 Allura Xper FD20 OR Table

OPTIONS

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Line #	Part #	Description	Qty	Each	Price	Initial

Travel & Accommodations for one (1) registered attendee. Includes one (1) participant's airfare from a North American customer location to a Philips North America Ultrasound Clinical Education training location with modest lodging, ground transportation and meal expenses for up to 3 days. Breakfast/dinner are provided by the hotel and lunch/breaks are catered by Philips Healthcare. All other expenses will be the responsibility of the attendee (ie. Baggage fees, meals while traveling, transportation to and from customer's home airport). Details are provided during the scheduling process.

1 DAY USCE ENT CES ONSITE

1 Day On-Site CES – Ultrasound training designed specifically to meet the customers' needs; one business day (up to 8 consecutive hours) with one of our Philips Clinical Education Specialists. Education is provided Monday-Friday during normal business hours.

*Note: Philips Healthcare personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. The training sessions should be attended by Ultrasound Sonographers as identified by the department director. Site must be patient-ready.

2 DAY USCE ENT 400lvl w/trav

2 Day 400 Level Tuition Only - Use only for a two-day level 400 Ultrasound Clinical Education course. Travel and lodging included. NOTE: A twenty-one (21) day notification of cancellation is required or education will be forfeited. Curriculum is subject to change without notice.

3	**NCVA092	**Lab Reporting**	1	$1,404.50	$1,404.50	_____

Lab Reporting allows the user to generate and print simple reports in modality stand-alone situations. The user is able to incorporate free text and clinical images. The reporting functionality is suited for local printing and email. Part of the report is generated automatically from administrative data (e.g. patient/exam data hospital name) and required data (e.g. run-log dose information and event-log).

4	**NCVA781	**Dicom Print compose**	1	$1,870.90	$1,870.90	_____

Dicom Print provides the possibility to interface to any DICOM Printer. This is an automated printing protocol. The option provides Print Manual Overrides, Print Job submission, and Print Job management.

5	**NCVA258	**CO2 View Trace Software**	1	$3,503.30	$3,503.30	_____

Software package which enables tracing (stacking) of images acquired with CO2 injections. This function can be used during postprocessing next to view trace of images acquired with iodine injection.

6	**NCVB171	**3D-RA R.6**	1	$43,168.50	$43,168.50	_____

100247 Allura Xper FD20 OR Table

OPTIONS

SELECTION OF ANY OPTION WILL INCREASE THE CONTRACT PRICE BY THE AMOUNT SHOWN IN THE PRICE COLUMN. OPTIONAL EQUIPMENT PRICING VALID ONLY IF PURCHASED IN CONJUNCTION WITH EQUIPMENT QUOTED.

Line #	Part #	Description	Qty	Each	Price	Initial

Allura 3D-RA assists physicians in decision making for treatment strategy in endovascular procedures, neuro or vascular surgery or even radiotherapy. Allura 3D-RA reduces the number of DSA acquisitions and fluoroscopy time needed to perform an examination. This means less X-Ray dose for the patient and the medical staff and a reduced quantity of dye, leading to reduced procedure costs. Allura 3D-RA provides a unique assessment after treatment due to the use of non-subtracted images that allows to shows devices stents, coils, clips and provide the optimal stand projection for endovascular treatment.
Allura 3D-RA provides a wide range of communication facilities to export 3D images.

1 Image Acquisition

- Image acquisition is performed with the Rotational Angiography feature of the Allura Xper FD series with the flexibility to position the C-arm in either head or side position.
- C-arm in Head position: the Rotational Angiography run is performed over a scan range of 240 degrees with a rotation speed up to 55 degrees/sec.
- C-arm in Side position: the Rotational Angiography run is performed over a scan range of 180 degrees with a rotation speed up to 30 degrees/sec.

2 3D Vessel Reconstruction

The rotational run is automatically transferred and displayed as a 3D vessel model: with the Real-Time digital link (option) 120 images are reconstructed into a 3 dimensional model within seconds. Additional reconstructions, using the Reconstructive Zooming Technique, can be performed as well.

3 Workflow:

- Allura 3D-RA in combination with the Allura Xper FD series will provide an optimal workflow via the following workflow enhancers:
  Complete automated 3D-RA process from 3D acquisition to 3D Viewing: no user interaction needed.
- 3D at Xper Module (option); With the Xper module the physician has all required 3D functionality at tableside. At the touch screen module functionality like rotating, panning, zooming, AVA, virtual stenting, 3D-APC and 3D Follow C-arc can be performed. With the mouse tablet all other functios can e performed so that there is is no need for the Physician to leave the examination room.
- 3D Automatic Position Control (3D-APC); When the optimal working position has been choosen via the Allura 3D-RA interventional tool, the C-arc will automatically steer to this position.
- 3D Follow C-arc; When the position of the C-arc (not using any X-ray) is changed, the 3D volume will automatically follow the position of the C-arc. This means the position of the C-arc (and therefore the 2D projection) and the 3D volume are always aligned. As last seen; when the user leaves the patient in the model and later selects that patient again, the Allura 3D-RA interventional tool will return to the image last used by the user.

OPTIONS

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Line #	Part #	Description	Qty	Each	Price	Initial

- Mouse over: When moving the mouse cursor over a button the mouse over text will show up to explain the function of that specific button.

4 Calibration

Allura 3D-RA calibrations are performed by Philips Healthcare Customer Support. Allura 3D-RA calibration data are stable over at least 6 months time.

5 Viewing

A Real Time user interface is available with 3D-RA, providing 3D object viewing in any space direction. A graphical display of (C-arm) stand position including

- angulation/rotation for any projection.
- Philips' CRM (Contrast Resolution Management) Technology for a considerable increase in contrast resolution in all volumes.
  Various Image Rendering possibilities: Volume/Surface Rendering, MIP, Endoscopy, SUM (pseudo x-ray image) Gradient rendering; the possibility to display the vessel structure transparently.
- Cut-plane function to get a precise insight of the shape of the pathology
- Orthoviewer providing a multi-planar visualization of objects using the different Image Rendering possibilities.
- MPR (Multi-Planar Reformatting): enables visualization of the volume in all three standard projections (coronal, sagital and axial) Especially useful for optimal viewing of spine procedures (e.g.Vertebroplasty)
- SpineView: special acquisition protocol for optimal viewing of the spine, especially osteoporotic vertebrae
  CalciView: allows visualization of Hyper dense plaque in 3D, separately or in relation to the lumen.
- 5 different distance measurements calculated in the same volume, including "Quick measurement" feature
- Volume calculation
  - Automated Vessel Analysis (AVA), provides information on vessel segment diameter, area and length with only three mouse-clicks. Endoscopic and cross sectional views are available.
- Computer Assisted Aneurysm Analysis (CAAA), providing information on Aneurysms, like volume, neck size etc..
- Catheter tip shape simulation, providing information on how to shape the catheter tip.
- Virtual stenting; Ability to simulate a stent placement in a selected vessel segment for proper stent sizing. All relevant data of the simulated stent are displayed
- Annotation: text can be added to a volume to capture comments.
- Interpolative Zoom
- Reconstructive Zooming Technique, 2 additional user defined reconstructions focused on the Volume Of Interest (VOI) using different cube size and voxel resolution.
- Subtraction of reconstructed volumes, allowing to visualize vessels without embolization devices (stents, coils, clips,..) to assess the outcomes of treatment
- Automatic Voxelshift: compensates for movement when rendering subtracted or superimposed volumes

OPTIONS

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Line #	Part #	Description	Qty	Each	Price	Initial

- Set the grey values WW/WL
- Store/Recall of user defined projections.

6 Archiving

Transfer to:

- Optional Hard Copy unit (DICOM Print)
- Any optional DICOM compatible device (e.g. PACS/ViewForum/Xcelera), supported are DICOM XA, DICOM SC, DICOM CT and DICOM 3D
- Any PC in a standard PC compatible format (JPEG,AVI)
- One or multiple DVD's, CD-ROM(s) for easy archiving
- Store a subset of exportable objects (snapshots and AVI Movies) to a USB removable memory device.

Clinical Education Program for 3DRA

CV 3DRA Handover OnSite Education:

Philips Education Specialists will provide sixteen (16) hours of education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. Note: Site must be patient-ready. Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref# 222-100615

7	**NCVB168	3D Roadmap	1	$37,248.40	$37,248.40	_____

3D Roadmap extends the capabilities of the integrated 3D product by providing a sustainable 3D roadmap to support interventional procedures. The 3D Roadmap option matches the real-time 2D fluoroscopy images with the 3D-RA reconstruction of the vessel tree. It provides a 3D real time insight of the advancement of the guide wire, catheter and coils through complex vessel structures. 3D roadmap has automatic motion compensation for the neuro runs. When the automatic motion compensation function is active, this functionality will constantly correct the motion artifacts which can be present in the 3D Roadmap image.

Image Acquisition
The 3D Roadmap is based on the visualization of the vessel tree out of 3D-RA. The 3D Roadmap is activated with one button touch at tableside (touch screen module). Select the 3D Roadmap function on the touch screen module, activate fluoroscopy and the 3D Roadmap is activated. The "live" 2D fluoroscopy image is overlaid with the 3D volume of the vessel tree and is automatically displayed on the 3D roadmap monitor in both the examination and control room.

Intuitive, fully controlled from tableside:
The bidirectional link between the X-ray system and the 3D Roadmap allows the user to select the optimal stand position for the procedure in two ways. 3D-APC (3D Automatic Position Control) allows the gantry to automatically move to the best interventional projection as shown on the 3D Roadmap monitor. 3D Follow C-arc allows the 3D Roadmap to remain in sync with the 2D projection, automatically adjusting viewpoint as the gantry is repositioned

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OPTIONS

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Line #	Part #	Description	Qty	Each	Price	Initial

- Land marking to adjust the intensity of the anatomical reference surrounding the vessels;
- 3D blending to fade in/out the 3D view;
- WW/WL settings to control the contrast/brightness;
- Store and review runs for reporting and archive purposes;
- Store snapshots and movies.

3D Roadmaps can be exported:
Any optional DICOM compatible device (e.g. PACS/ViewForum/Xcelera), supported are DICOM XA, DICOM SC, DICOM CT and DICOM 3D
Any PC in a standard PC compatible format (JPEG,AVI)

And stored/archieved on
A PACS systems as DICOM Secondary Capture images or movies
USB device
One or multiple DVD's, CD-ROM(s) for easy archiving
Hard copy via the (DICOM Print) protocol

8	**NCVB167	MR/CT Roadmap	1	$21,624.00	$21,624.00	_____

MR/CT Roadmap extends the capabilities of the integrated 3D product by providing a sustainable 3D roadmap based on previous acquired CT or MR scans to support interventional procedures. The MR/CT Roadmap option matches the real-time 2D fluoroscopy images with the 3D volume of CT or MR.

The CT or MR data can visualize in either 3D (e.g vascular structure) or with 2D slice in the same orientation as the 2D fluoro image. It provides a 3D real time insight of the advancement of the guide wire, catheter and coils through complex vessel and anatomical structures

Image Acquisition
A previously acquired CT or MR scan can be imported into the system and matched with a low dose 3D-RA or XperCT scan The MR/CT Roadmap is activated with one button touch at tableside (touch screen module). Select the MR/CT Roadmap function on the touch screen module, activate fluoroscopy and the MR/CT Roadmap is activated. The "live" 2D fluoroscopy image is overlaid with the MR/CT volume presented in 2D or 3D and is automatically displayed on the roadmap monitor in both the examination and control room.
Intuitive, fully controlled from tableside:
The bidirectional link between the X-ray system and the MR/CT Roadmap allows the user to select the optimal stand position for the procedure in two ways. 3D-APC (3D Automatic Position Control) allows the gantry to automatically move to the best interventional projection as shown on the MR/CT Roadmap monitor. 3D Follow C-arc allows the MR/CT Roadmap to remain in sync with the 2D projection, automatically adjusting viewpoint as the gantry is repositioned.

- Easy 2 step registration of the MR/ CT volumes
- Landmarking to adjust the intensity of the anatomical reference surrounding the vessels and tissue
- 2D and 3D blending to fade in/out the 2D or 3D view;
- WW/WL settings to control the contrast/brightness;
- Store and review runs for reporting and archive purposes;
- Store snapshots and movies.

MR/CT Roadmaps can be exported:

- Any optional DICOM compatible device (e.g. PACS/ViewForum/Xcelera), supported are DICOM

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Line #	Part #	Description	Qty	Each	Price	Initial
		XA, DICOM SC, DICOM CT and DICOM 3D. • Any PC in a standard PC compatible format (JPEG,AVI). And stored/archieved on • A PACS systems as DICOM Secondary Capture images or movies. • USB device. • One or multiple DVD's, CD-ROM(s) for easy archiving. • Hard copy via the (DICOM Print) protocol.				
9	**FCV0569	**Coupling to Video Switching** Coupling to Video Switching A video splitter box is provided to enable coupling a maximum of 4 color outputs (e.g. Interventional tools, Xcelera, XperIM and Viewforum) to the switching concept from our partner. ! For each color output that is coupled to the splitter box, one wall connection box becomes redundant.	1	$8,071.90	$8,071.90	_____
10	**NCVB947	**XL screen video-share slaving** The XL screen video-share interface enables to share all information being presented on the large 56-inch screen in the Examination Room. The XL screen video-share interface provides two, simultaneously available, video outputs: • A full resolution video-output (Quad HD = 3840*2160 ; 8 MegaPixel) • A downscaled resolution video-output (HD = 1920*1080 ; 2 MegaPixel). The full resolution 8MP video-output is compatible with the following Dual DVI 3rd party monitors: • Barco 56-inch: CML5682W4 • Eizo 56-inch: Radiforce LS560W • Eizo 60-inch: Radiforce LX600W The downscaled 2MP resolution video-output can be used to connect to a (3rd party) HD display or to a 3rd party recording/streaming/reviewing solution. Note: The information provided at the 3rd party monitors (2 & 8MP) video output cannot be used for diagnostic purposes.	1	$13,615.70	$13,615.70	_____
11	**NCVB591	**2ND REF for FlexVision XL** 2nd REF for FlexVision XL is optional on FlexVision XL. Second Ref images will be displayed on the large screen monitor.	1	$5,835.30	$5,835.30	_____
12	**980406190009	**PIVOTING TABLE-MOUNTED RADIATION SHIELD**	1	$2,915.00	$2,915.00	_____

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Line #	Part #	Description	Qty	Each	Price	Initial

Table-mounted radiation shield for additional protection of physician and staff against scatter radiation. The shield consists of two protective parts: a lower shield and an upper shield. The shield is specially designed for use with the AD5 patient table.

The table mounted radiation shield provides the following features:

- Mounting to either the right orleft tableaccessory rails;
- Pivoting into the required working position;
- Pivoting into the parking underneath the tabletop facilitating patient preparation;
- The upper shield can be positioned upright providing optimal protection or can be folded down for free access to the patient.

The table mounted radiation shield includes:

- Lower shield measuring 70 cm high 80 cm wide 0.5 mm Pbequivalence;
- Upper shield measuring 40 cm high 50 cm wide 0.5 mm Pbequivalence;
- Mounting clamp;

Docking device for wall mounting.

13	****989801220202**	**CORE Precision Guided Therapy System**	**1**	**$92,750.00**	**$92,750.00**	_____

CORE Precision Guided Therapy System

CORE CPU, Operator's Manual, Power Transformer, Cable Pre-Install Kit, Connection Box, two (2) Standard Controller and one (1) bedrail mount, 19"NEC Monitor Kit, Phased Array PIM Body, FFR functionality, DICOM Network Connection, ChromaFlo Functionality.

-Includes VH IVUS End User License Agreement

The customer agrees that use of the VH IVUS Software is subject to the terms of the End User License Agreement. A copy of the End User License Agreement is also available from your VOLCANO representative or online at www.volcanocorp.com/products/pdf-files/sofware-support-vh-ivus.pdf

-Includes Three (3) Year IVUS Software Support Agreement

This signed Agreement provides for the purchase of the IVUS Software Support Agreement (SSA), which provides for unspecified IVUS software revisions released during for a three (3) year term (should any be commercially released) at no additional cost. In the absence of an SSA, future software revision releases will be made available at additional cost to be determined upon commercial availability.

14	****989801220211**	**CORE™ Control Pad Option**	**1**	**$9,937.50**	**$9,937.50**	_____

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Line #	Part #	Description	Qty	Each	Price	Initial
		CORE Control Pad Option				
		Bedside touchscreen controller offering system control from the sterile field				

PHILIPS PRODUCT WARRANTY

CARDIOVASCULAR (CV) SYSTEMS

This product warranty document is an addition to the terms and conditions set forth in the quotation to which this warranty document is attached. The terms and conditions of the quotation are incorporated into this warranty document. The capitalized terms herein have the same meaning as set forth in the quotation.

TWELVE-MONTH SYSTEM WARRANTY
Philips warrants to Customer that the Philips Vascular and Cardiac Systems (the "System") as delivered to Customer will perform in substantial compliance with its performance specifications for a period of twelve (12) months upon first patient use. Any glassware or flat detectors provided with the System is subject to special warranty terms set forth below.

PLANNED MAINTENANCE
During the warranty period, Philips personnel will schedule planned maintenance visits, in advance, at a mutually agreeable time on weekdays, between 8:00 A.M. and 5:00 P.M. local time, excluding Philips observed holidays.

SYSTEM UPGRADES
Any commercially available upgrade to the System which is hereafter installed by Philips during the original term of the System warranty shall be subject to the warranty terms contained in the first paragraph of this warranty, except that such warranty shall expire on the later of: a) upon termination of the initial twelve (12) month warranty period for the System on which the upgrade is installed or b) after ninety (90) days for parts only from the date of installation.

MRC X-RAY TUBES
Philips warrants to Customer, for the warranty periods further specified in this section, that the Philips X-Ray tube will be substantially free from defects in material and manufacturing workmanship, which impair performance under normal use as specified in Philips product descriptions and specifications.

The warranty period for MRC tubes provided with Customer's purchase of a new or refurbished X-ray system shall be the shorter of thirty-six (36) months after installation or thirty-eight (38) months after date of shipment from Philips. The warranty period for purchases of replacement tubes shall be the shorter of twelve (12) months after installation or fourteen (14) months after date of shipment from Philips.

MRC TUBE WARRANTY EXCLUSION
The above warranty shall not apply to X-ray tubes outside the United States and Canada. Philips' obligations under the product warranty do not apply to any product defects resulting from: improper or inadequate maintenance or calibration by Customer or its agents; Customer or third party supplied software, interfaces, or supplies; use or operation of the product other than in accordance with loss, or damage in transit; improper site preparation; unauthorized maintenance or Philips' applicable product specifications and written instructions; abuse, negligence, accident, modifications to the product; or, to viruses or similar software interference resulting from the connection of the product to a network.

MRC TUBE WARRANTY REMEDIES
If a tube is found to fail during the warranty period, and if, in the best judgment of Philips, the failure is not due to neglect, accident, improper installation, use contrary to instructions, or the exclusions stated above, Philips' tube warranty liability hereunder is limited to, at Philips option, the repair or replacement of the tube. Any replacement tube would have a warranty period equal to the balance of the warranty period left on the tube replaced.

IMAGE INTENSIFIER TUBES
Philips warrants the image intensifier tubes provided with the System, if any, will be free from defects in material and manufacturing workmanship for twenty-four (24) months. Claims must be made within twenty-four (24) months after installation or twenty-seven (27) months after date of shipment from Philips, whichever occurs first. If an image intensifier tube fails to meet this warranty, as Customer's sole and exclusive remedy, upon return of the tube, Philips will provide a prorated credit towards the purchase of a replacement tube from Philips as follows:

USAGE				CREDIT
0	to within	12	months	100%
12	to within	13	months	50%
13	to within	14	months	46%
14	to within	15	months	42%
15	to within	16	months	37%
16	to within	17	months	33%
17	to within	18	months	29%
18	to within	19	months	25%
19	to within	20	months	21%
20	to within	21	months	17%
21	to within	22	months	12%
22	to within	23	months	8%
23	to within	24	months	4%

Tubes received by Philips under this warranty that are found to meet all test specifications will be returned to the Customer and the warranty will continue as of the original date of installation. Examination of the returned tube may necessitate its destruction, but Philips' liability shall, in any case be limited to repair or replacement as aforesaid, only if in its sole opinion the tube has been properly used, installed and applied and has not been subjected to neglect, accident, or improper installation, or use. Transportation charges and risk of loss, both ways, of returned or replaced tubes shall be at the expense of the Customer.

DYNAMIC FLAT DETECTORS
Philips warrants the flat detectors provided with the System, if any, will be free from defects in material and manufacturing workmanship for twelve (12) months. Claims must be made within twelve (12) months after installation or fifteen (15) months after date of shipment from Philips, whichever occurs first. If a detector fails to meet this warranty, as Customer's sole and exclusive remedy, upon return of the detector, Philips will provide Customer a replacement detector at no additional charge.

SYSTEM SOFTWARE AND SOFTWARE UPDATES
The software provided with the System will be the latest version of the standard software available for that System as of the 90th day prior to the date the System is delivered to Customer. Updates to standard software for the System that do not require additional hardware or equipment modifications will be performed as a part of normal warranty service during the term of the warranty.

All software is and shall remain the sole property of Philips or its software suppliers. Use of the software is subject to the terms of a separate software license agreement. Customer must sign all such license agreements prior to or upon the delivery of the product. No license or other right is granted to Customer or to any other party to use the software except as set forth in the license agreements.

Any Philips maintenance or service software and documentation provided with the product and/or located at Customer's premises is intended solely to assist Philips and its authorized agents to install and to test the System, to assist Philips and its authorized agents to maintain and to service the System under a separate support agreement with Customer, or to permit Customer to maintain and service the System. Customer agrees to restrict the access to such software and documentation to Philips' employees and those of its authorized agents, and to authorized employees of Customer only.

WARRANTY LIMITATIONS
Philips' obligations under the System warranty are limited, at Philips' option, to the repair or the replacement of the System or a portion thereof, or to a credit or refund of a portion of the purchase price paid by Customer. Any refund or credit will be paid to Customer when the System is returned to Philips. Certain of the parts used in the manufacture or installation of, or in the replacement parts for, this System may contain refurbished components. If such components are used, they will be subject to the same quality control and inspection procedures as all other components in the System. Any System warranty is made on condition that Philips receives written notice of a System defect during the warranty period, and within thirty (30) days following the discovery of the defect by Customer. Philips' obligations under the System warranty do not apply to any System defects resulting from: improper or inadequate maintenance or calibration by Customer or its agents; Customer or third party supplied software, interfaces, or supplies; use or operation of the product other than in accordance with loss, or damage in transit; improper site preparation; unauthorized maintenance or Philips' applicable product specifications and written instructions; abuse, negligence, accident, modifications to the System; or to viruses or similar software interference resulting from the connection of the product to a network. Philips does not provide a warranty for any such third party products furnished to Customer by Philips; however, Philips shall use reasonable efforts to extend to Customer the third party warranty for the product. The obligations of Philips described above are Philips' only obligations and Customer's sole and exclusive remedy for a breach of a System warranty. Repairs or replacement parts do not extend the term of this warranty.

THE WARRANTIES SET FORTH IN THIS WARRANTY DOCUMENT WITH RESPECT TO THE SYSTEM (INCLUDING THE SOFTWARE PROVIDED WITH THE SYSTEM), GLASSWARE, AND DETECTORS ARE THE ONLY WARRANTIES MADE BY PHILIPS IN CONNECTION WITH THE SYSTEM, SOFTWARE, GLASSWARE, DETECTORS, AND THE TRANSACTIONS CONTEMPLATED BY THE QUOTATION, AND ARE EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ACCESS TO SYSTEM
Philips shall have full, free and safe access to the System and Customer's operation, performance and maintenance records for the System, on each scheduled or requested warranty service visit. Philips shall also have access to and use of any machine, service, attachment, features or other equipment required to perform the necessary service contemplated herein at no charge to Philips. Customer waives warranty service if it does not provide such access to the System and Customer's records. Should Philips be denied access to the System and Customer's records at the agreed upon time, a charge equal to the appropriate hourly rate will be accepted by Customer for "waiting time."

WARRANTY SERVICE
In the event it is not possible to accomplish warranty service within normal working hours (8:00 A.M. to 5:00 P.M., Monday through Friday, excluding Philips observed holidays), or in the event Customer specifically requests that warranty service be performed outside of Philips normal working hours, Customer agrees to pay for such services at Philips standard service rates in effect. Maintenance Agreements are available for extended coverage.

TRANSFER OF SYSTEM
In the event Customer transfers or relocates the System, all obligations under this warranty will terminate unless Customer receives the prior written consent of Philips for the transfer or relocation. Upon any transfer or relocation, the System must be inspected and certified by Philips as being free from all defects in material, software and workmanship and as being in compliance with all technical and performance specifications. Customer will compensate Philips for these services at the prevailing service rates in effect as of the date the inspection is performed. Any System which is transported intact to pre-approved locations and is maintained as originally installed in mobile configurations will remain covered by this warranty.

CONDITIONS
This warranty is subject to the following conditions: the System (a) is to be installed by authorized Philips representatives (or is to be installed in accordance with all Philips installation instructions by personnel trained by Philips), (b) is to be operated exclusively by duly qualified personnel in a safe and reasonable manner in accordance with Philips written instructions and for the purpose for which the products were intended, (c) is to be maintained and in strict compliance with all recommended and scheduled maintenance instructions provided with the System, and (d) Customer is to notify Philips immediately in the event the System at any time fails to meet its printed performance specifications.

LIMITATIONS OF LIABILITY AND DISCLAIMERS
The liability, if any, of Philips AND ITS AFFILIATES for damages whether arising from breach of the terms in the quotation, breach of warranty, negligence, indemnity, strict liability or other tort, or otherwise with respect to the products and services is limited to an amount not to exceed the price of the product or service giving rise to the liability.

IN NO EVENT SHALL PHILIPS OR ITS AFFILIATES BE LIABLE FOR ANY INDIRECT, PUNITIVE, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES, INCLUDING WITHOUT LIMITATION, LOST REVENUES OR PROFITS, OR THE COST OF SUBSTITUTE PRODUCTS OR SERVICES WHETHER ARISING FROM BREACH OF THE TERMS IN THIS QUOTATION, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT. PHILIPS SHALL HAVE NO LIABILITY FOR ANY GRATUITOUS ADVICE PROVIDED TO THE CUSTOMER.

FORCE MAJEURE
Philips and Customer shall each be excused from performing its obligations arising from any delay or default caused by events beyond its reasonable control including, but not limited to: acts of God, acts of third parties, acts of the other party, acts of any civil or military authority, fire, floods, war, embargoes, labor disputes, acts of sabotage, riots, accidents, delays of carriers, subcontractors or suppliers, voluntary or mandatory compliance with any government act, regulation or request, shortage of labor, materials or manufacturing facilities.

Philips system specifications are subject to change without notice Document Number 4535 983 03234 999

SUPPLEMENTAL #1
February 25, 2016
406 pm

ATTACHMENT 3B
REVISED EQUIPMENT CHARTS AND PAGES

SUPPLEMENTAL #1

February 25, 2016
406 pm

Equipment > $50,000	Qty	Unit Cost	Total Cost	Maintenance	Total Equipment
iMRI systems	1	3,959,767	3,959,767	705,180	4,664,947
Linear Accelerator	1	2,400,000	2,400,000	950,727	3,350,727
Optimize Hybrid OR Imaging Program	1	1,972,443	1,972,443	375,300	2,347,743
Skytron Surgical Lighting System	1	135,910	135,910		135,910
Maclab Hybrid OR	1	229,494	229,494		229,494
Hyrbid Suite	1	230,000	230,000		230,000
Injector	1	25,000	25,000		25,000
Navigation System Allocation	1	500,000	500,000		500,000
Chemistry Analyzer	2	500,000	1,000,000		1,000,000
Hemotology Analyzers	2	500,000	1,000,000		1,000,000
Automated DNA Extractor	2	500,000	1,000,000		1,000,000
PCR Equipment Allocation	2	500,000	1,000,000		1,000,000
Blood Irradiator	1	500,000	500,000		500,000
R&F Room	2	350,000	700,000		700,000
Pharmacy Carousel	3	250,000	750,000		750,000
Automated Chemistry Line	1	250,000	250,000		250,000
Automated Hemotology Line	1	250,000	250,000		250,000
Immunoassay Analyzer	2	250,000	500,000		500,000
Serology Analyzer	2	250,000	500,000		500,000
Electrophoresis Analyzer	2	250,000	500,000		500,000
Cellavision Analyzer	1	250,000	250,000		250,000
Coagulation Analyzer	2	250,000	500,000		500,000
Flow Cytometer	2	250,000	500,000		500,000
iMRI Systems Surgical Instruments	1	150,000	150,000		150,000
Anaerobic Chamber	1	150,000	150,000		150,000
Urine Analyzer	2	100,000	200,000		200,000
Dispensor, Medication	10	80,000	800,000		800,000
Centralized RO	1	60,000	60,000		60,000
Critical Care Patient Bed	30	55,000	1,650,000		1,650,000
Perfusion Pumps	6	50,000	300,000		300,000
OR Integration System Allocation	20	50,000	1,000,000		1,000,000
Video Tower Allocation	15	50,000	750,000		750,000
MRI Contrast Injector	2	50,000	100,000		100,000
Stress Test Treadmill	1	50,000	50,000		50,000
Hot Lab Hood	2	50,000	100,000		100,000
Blood Culture Analyzer	8	50,000	400,000		400,000
			24,362,614	2,031,207	26,393,821

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ATTACHMENT 4A
MRI CRITERIA

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Project-Specific Review Criteria: Magnetic Resonance Imaging (MRI) Services

1. **Utilization Standards for non-Specialty MRI Units.**
   a. **An applicant proposing a new non-Specialty stationary MRI unit should project a minimum of at least 2160 MRI procedures in the first year of service, building to a minimum of 2520 procedures per year by the second year of service, and building to a minimum of 2880 procedures per year by the third year of service and for every year thereafter.**

The criteria do not seem appropriate or applicable. The project is for an iMRI which is a special- use MRI that is used in the operating room. A part of this proposal is the addition of an intraoperative magnetic resonance imaging (iMRI) unit for use in the neurosurgery operating room. This equipment will be used to assist neurosurgeons in the resection of brain tumors initially. Without this technology, MRI testing must be done in the hospital's radiology department post-operatively. This delayed imaging could identify the further need for surgery and the patient will have to undergo a subsequent surgery. iMRI is advanced technology in medicine that bridges the specialties of surgery and radiology. With this technology, the precision and success of surgical treatment of epilepsy and brain tumor removal increase.

Le Bonheur Children's Hospital, part of the Methodist Healthcare-Memphis Hospitals currently operates an iMRI. In 2014, they performed 92 iMRIs and 122 last year. Their experience shows that about 50% of brain tumor resections receive an iMRI scan. Projections for the project assume 50% of current brain tumor surgeries (322 surgeries) will receive a scan. MRIs are projected with minimal growth of 1.5% through Year 2 as are iMRIs from Year 1 to Year 2.

TABLE 1
PROJECTED MRI UTILIZATION

	2013	2014	2015		Year 1 2019	Year 2 2020
MRI Procedures	9,803	10,524	11,130		11,813	11,990
iMRI Procedures	0	0	0		166	168
Total Procedures	9,803	10,524	11,130		11,979	12,159

   b. **Providers proposing a new non-Specialty mobile MRI unit should project a minimum of at least 360 mobile MRI procedures in the first year of service per day of operation per week, building to an annual minimum of 420 procedures per day of operation per week by the second year of service, and building to a minimum of 480 procedures per day of operation per week by the third year of service and for every year thereafter.**

Not applicable; applicant is proposing fixed equipment.

c. **An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for MRI units are developed. An applicant must demonstrate that the proposed unit offers a unique and necessary technology for the provision of health care services in the Service Area.**

Methodist University hosts a busy surgical brain tumor program performing over 300 annually. With the main goal of brain tumor surgery being to maximize resection while preserving function, Methodist continues to implement the most current surgical assistive technology.

Intraoperative imaging can provide the updated information to maintain accurate navigation during surgery. Currently, the practice to confirm that a complete resection has been accomplished and to ensure no unrecognized complication has arisen is to close the surgical field, transfer the patient to ICU and complete an MRI the following day. If any tumor remains, or there are complications noted, the neurosurgeon may take the patient back for re-operation. The use of intraoperative imaging allows this confirmation to be completed prior to closing of the original surgery and thus avoiding the risk of additional surgery.

As the intraoperative imaging of choice, iMRI affords the possibility of more accurate and complete resections while decreasing the risk of additional surgery and complications. While iMRI primarily serves a very unique purpose, patient population and limited volume, it allows for increased surgical success and therefore increased length of survival for patients with brain tumors.

Just as iMRI is pivotal in brain tumor surgery, it may also be utilized for epilepsy surgery, intra-cranial cyst surgery, brain biopsy, catheter placement and intra-cranial vascular surgery.

d. **Mobile MRI units shall not be subject to the need standard in paragraph 1 b if fewer than 150 days of service per year are provided at a given location. However, the applicant must demonstrate that existing services in the applicant's service area are not adequate and/or that there are special circumstances that require these additional services.**

Not applicable; applicant is proposing fixed equipment.

e. **Hybrid MRI units. The HSDA may evaluate a CON application for an MRI "hybrid" Unit (an MRI Unit that is combined/utilized with another medical equipment such as a megavoltage radiation therapy unit or a positron emissions tomography unit) based on the primary purposes of the Unit.**

Not applicable; applicant is not proposing "hybrid" equipment.

2. **Access to MRI Units. All applicants for any proposed new MRI Unit should document that the proposed location is accessible to approximately 75% of the Service Area's population. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRI units that service the non-**

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Tennessee counties and the impact on MRI unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).

This is special-use equipment that will be used for brain tumor surgeries. The 45-minute drive time does not seem appropriate for such high acuity surgeries.

Yet, as noted in the application, the project primary service area includes Shelby County, TN, DeSoto County, MS and Crittenden County, AR.

The majority (81%) of the population in the Methodist service area is in Shelby County. See Table 2 below for the 2015 population analysis by county. Also, please see the drive time map in Figure 1. The 45-minute drive time radius for the Methodist MRI services at Methodist University Hospital covers all of Shelby County and the majority of DeSoto and Crittenden counties.

TABLE 2
POPULATION BY COUNTY, 2015
METHODIST SERVICE AREA

Service Area	Population	% of Total
Shelby, TN	946,637	81%
DeSoto, MS	168,989	15%
Crittenden, AR	48,531	4%
Total	1,164,157	100%
Source: Truven Healthcare Analytics- Market Expert		

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FIGURE 1
DRIVE TIME MAP, 45-MILE RADIUS

3. **Economic Efficiencies. All applicants for any proposed new MRI Unit should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.**

   Alternate services and technologies were investigated. The current practice of performing the MRI post-surgery is not optimal. As noted in the response to 1.c. above, the iMRI affords the possibility of more accurate and complete resections while decreasing the risk of additional surgery and complications.

4. **Need Standard for non-Specialty MRI Units.**
   A need likely exists for one additional non-Specialty MRI unit in a Service Area when the combined average utilization of existing MRI service providers is at or above 80% of the total capacity of 3600 procedures, or 2880 procedures, during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per MRI unit is based upon the following formula:

   Stationary MRI Units: 1.20 procedures per hour x twelve hours per day x 5 days per week x 50 weeks per year = 3,600 procedures per year

   Mobile MRI Units: Twelve (12) procedures per day x days per week in operation x 50 weeks per year. For each day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of the total capacity of 600 procedures per year.

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The combined average utilization of existing fixed MRI units in the service area is 2,770 in 2014. Yet, St. Jude Children's Research Hospital is an internationally recognized center of excellence dedicated to research and treatment for children with cancer and other catastrophic diseases. St. Jude is caring for a unique population of patients. Excluding St. Jude's volumes and equipment from the market calculation, the average for MRI volumes per fixed unit is 2,845 in 2014 which is at the threshold.

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TABLE 3
UTILIZATION OF MRI EQUIPMENT 2012-2014

	2012		2013		2014	
Fixed Equipment	**Proc**	**# of Units**	**Proc**	**# of Units**	**Proc**	**# of Units**
Hospital-Based Equipment (HOSP)						
Baptist Memorial Hospital - Collierville	1,734	1	1,593	1	1,753	1
Baptist Memorial Hospital - Memphis	11,913	3	11,280	3	10,701	3
Baptist Memorial Hospital - Women	N/A	N/A	72	1	251	1
Baptist Rehabilitation - Germantown	1,596	1	1,212	1	1,107	1
Delta Medical Center	787	1	674	1	983	1
Le Bonheur Children's Medical Center *	5,289	2	5,260	2	5,340	2
Methodist Healthcare - Germantown Hospital	6,557	2	6,892	2	6,904	2
Methodist Healthcare - South Hospital	4,139	1	4,090	1	3,487	1
Methodist Healthcare-North Hospital	6,092	2	6,003	2	6,415	2
Methodist Healthcare-University Hospital	9,803	3	10,524	3	11,130	3
Regional Medical Center /Medical Center MRI	4,491	1	4,131	1	4,109	1
St. Francis Hospital	5,393	3	5,326	3	5,045	3
St. Francis Hospital - Bartlett	3,642	2	3,518	2	3,559	2
St. Jude Children's Research Hospital	8,737	4	8,305	3	8,377	4
Methodist Healthcare - Olive Branch Hospital	N/A	N/A	54	1	1,551	1
Baptist Memorial Hospital - DeSoto	7,388	3	7,021	3	N/A	N/A
Non-Hospital-Based Equipment						
Baptist Rehabilitation - Germantown (Briarcrest)	650	1	613	1	492	1
Campbell Clinic - Union (1st year 2010)	2,155	1	2,539	1	2,738	1
Campbell Clinic	6,321	1	5,547	1	5,923	1
Diagnostic Imaging PC - Memphis	6,538	1	6,737	1	6505	1
MSK Group PC - New Covington Pike	3,140	1	3,013	1	3,034	1
MSK Group PC - Briarcrest **	4,489	-	4,637	-	4,439	-
Neurology Clinic, PC	3,160	1	3,312	1	2,577	1
Outpatient Diagnostic Center of Memphis	2,214	1	2,563	1	2,889	1
Park Avenue Diagnostic Center	2,681	2	2,075	2	3,188	2
Semmes-Murphey Clinic (Humphreys Blvd)	6,490	2	6,277	2	6,879	2
Wesley Neurology Clinic, P.C. **	1,309	-	1,026	-	1,307	-
West Clinic, P.C	1,564	1	1,287	1	1,655	1
Methodist Diagnostic Center - Olive Branch	2,054	1	1,601	1	n/a	n/a
Methodist Diagnostic Center - Southaven	2,340	1	2,418	1	n/a	n/a
DeSoto Imaging Specialists	3,141	1	3,562	1	n/a	n/a
Subtotal Fixed Equipment	**125,807**	**44**	**123,162**	**45**	**110,787**	**40**
Average Procedures per Unit	**2,859**		**2,737**		**2,770**	

Subtotal Fixed Equipment without St. Jude	**117,070**	**40**	**114,8577**	**42**	**102,410**	**36**
Average Procedures per Unit without St. Jude	**2,927**		**2,735**		**2,845**	

Source: Medical Equipment Registry (as of 8/10/2015) and Mississippi State Health Plan 2014-2015

*Note: Le Bonheur Children's Hospital has two standard pediatric MRIs and an iMRI which is used specifically for neurosurgery. Volumes for the iMRI are excluded.

** Note: Baptist Rehab Briarcrest equipment is shared with MSK Group Briarcrest and Neurology Clinic PC equipment is shared with Wesley Neurology Clinic, therefore the number of units is not listed to truly reflect the number of MRIs in the service area.

Please see an update on Le Bonheur Children's Hospital project (CN1311-042A) at 100 N. Humphreys is currently in the middle of Phase II construction with expectations of being complete this summer – July or August 2016. Phase I, which includes clinical and lobby space, are currently occupied and in use.

5. **Need Standards for Specialty MRI Units**

All of question 5 is not applicable; applicant is not proposing one of these noted Specialty MRI units. The unit is a special-use MRI as noted throughout this response.

a. **Dedicated fixed or mobile Breast MRI Unit. An applicant proposing to acquire a dedicated fixed or mobile breast MRI unit shall not receive a CON to use the MRI unit for non-dedicated purposed and shall demonstrate that annual utilization of the proposed MRI unit in the third year of operation is projected to be at least 1,600 MRI procedures (.80 times the total capacity of 1 procedure per hour times 40 hours per week times 50 weeks per year), and that:**

1. **It has an existing and ongoing working relationship with a breast-imaging radiologist or radiology proactive group that has experience interpreting breast images provided by mammography, ultrasound, and MRI unit equipment, and that is trained to interpret images produced by an MRI unit configured exclusively for mammographic studies;**
2. **Its existing mammography equipment, breast ultrasound equipment, and the proposed dedicated breast MRI unit is in compliance with the federal Mammography Quality Standards Act;**
3. **It is part of an existing healthcare system that provides comprehensive cancer care, including radiation oncology, medical oncology, surgical oncology and an established breast cancer treatment program that is based in the proposed service area.**
4. **It has an existing relationship with an established collaborative team for the treatment of breast cancer that includes radiologists, pathologists, radiation oncologists, hematologist/oncologists, surgeons, obstetricians/gynecologists, and primary care providers.**

b. **Dedicated fixed or mobile Extremity MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Extremity MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable**

of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity. Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Extremity MRI Unit and a CON granted for this use should so state on its face.

c. **Dedicated fixed or mobile Multi-position MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Multi-position MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity. Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Multi-position MRI Unit and a CON granted for this use should so state on its face.**

6. **Separate Inventories for Specialty MRI Units and non-Specialty MRI Units. If data permits, Breast, Extremity, and Multi-position MRI Units shall not be counted in the inventory of non-Specialty fixed or mobile MRI Units, and an inventory for each category of Specialty MRI Unit shall be counted and maintained separately. None of the Specialty MRI Units may be replaced with non-Specialty MRI fixed or mobile MRI Units and a Certificate of Need granted for any of these Specialty MRI Units shall have included on its face a statement to that effect. A non-Specialty fixed or mobile MRI Unit for which a CON is granted for Specialty MRI Unit purpose use-only shall be counted in the specific Specialty MRI Unit inventory and shall also have stated on the face of its Certificate of Need that it may not be used for non-Specialty MRI purposes.**

   Not applicable; applicant is not proposing one of the Specialty MRI units as listed above. This is a special-use MRI for operating room use as described in this response.

7. **Patient Safety and Quality of Care. The applicant shall provide evidence that any proposed MRI Unit is safe and effective for its proposed use.**

   a. **The United States Food and Drug Administration (FDA) must certify the proposed MRI Unit for clinical use.**

      See Attachment 4A-1 for FDA certification.

   b. **The applicant should demonstrate that the proposed MRI Procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.**

      The architect consulted on this project confirms that the physical environment will conform to all applicable federal standards, manufacturer's specifications and licensing agencies' requirements. See Attachment 8B for the revised architect's letter.

   c. **The applicant should demonstrate how emergencies within the MRI Unit facility will be managed in conformity with accepted medical practice.**

The unit will be on the Methodist University Hospital campus. There are clinical technicians and emergency personnel on the premises trained in basic life support when the patient is being scanned. In the event of cardiac or respiratory arrest, trained clinical personnel will initiate basic life support while the patient is being emergently removed from the scan room, and then taken to be treated by appropriate physicians and clinicians.

d. **The applicant should establish protocols that assure that all MRI Procedures performed are medically necessary and will not unnecessarily duplicate other services.**

There are established standard protocols in place for Methodist to ensure all MRI procedures are medically necessary and will not unnecessarily duplicate other services. All MRI procedures are required to have a physician's written order that defines the medical necessity. All orders will be reviewed to ensure that there is no unnecessary duplication of services. Methodist has a dedicated team of nurses that precertify all MRI procedures through the various third party payers. The rigorous precert process ensures medical necessity and assures that the patient does not receive duplicative procedures. See Attachment 4C for the System Policy outlining the guidelines for a physician order for all diagnostic services.

e. **An applicant proposing to acquire any MRI Unit or institute any MRI service, <u>including</u> Dedicated Breast and Extremity MRI Units, shall demonstrate that it meets or is prepared to meet the staffing recommendations and requirements set forth by the American College of Radiology, or a comparable accreditation authority for MRI within two years following operation of the proposed MRI Unit.**

Methodist University Hospital is fully accredited by the American College of Radiology (ACR). Methodist meets the staffing and quality assurance requirements.

f. **All applicants shall commit to obtain accreditation from the Joint Commission, the American College of Radiology, or a comparable accreditation authority for MRI within two years following operation of the proposed MRI Unit.**

Methodist University Hospital is fully accredited by the Joint Commission.

g. **All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.**

The need for a transfer agreement is not applicable; the equipment will be located on the Methodist University Hospital campus.

The physician medical director is an active member of the medical staff. See Attachment Section Services 4A-2 for current medical director's CV.

8. **The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.**

Methodist assures the HSDA that all data requested to maintain the Equipment Registry will be submitted within the expected time frame.

9. **In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:**

a. **Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;**

Not applicable.

b. **Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or**

Not applicable.

c. **Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.**

Methodist is certified for both Medicare and TennCare/Medicaid and participates in both programs. Methodist contracts with all of the TennCare plans offered in the service area and with Medicaid in adjoining States. All Methodist hospitals treat TennCare participants under the system's TennCare contracts.

In comparison to other large counties across the State, Shelby County is the home to a disparate number of low-income families seeking coverage from the state's Medicaid program. Methodist is one of the largest health care providers of TennCare in the State and is committed to these patients as reflected in the projections for this proposal.

d. **Who is proposing to use the MRI unit for patients that typically require longer preparation and scanning times (e.g. pediatric, special needs, sedated, and contrast agent use patients). The applicant shall provide in its application information supporting the additional time required per scan and the impact on the need standard.**

See response to 1.c. above for the description of the special-use of the iMRI.

ATTACHMENT 4A-1
FDA CERTIFICATION
iMRI

SEP 30 2011

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	September 30, 2011
Submitter:	GE Healthcare, (GE Healthcare Japan Corporation) 7-127, Asahigaoka 4-chome, Hino-shi, Tokyo 191-8503 JAPAN
Primary Contact Person:	Toru Shimizu Regulatory Affairs Specialist GE Healthcare, (GE Healthcare Japan Corporation) Telephone: +81-42-585-5344 Fax: +81-42-585-5075
Secondary Contact Person:	Glen Sabin Regulatory Affairs Director GE Healthcare, (GE Medical Systems, LLC) Telephone: (262) 521-6848 Fax: (262) 521-6439
Device: Trade Name:	Discovery MR750w 3.0T
Common/Usual Name:	Magnetic Resonance Imaging System
Classification Names: Product Code:	Magnetic resonance diagnostic device LNH
Predicate Device(s):	Discovery MR750 (K081028) Optima MR450w (K091536)
Device Description:	The Discovery MR750w 3.0T features a superconducting magnet operating at 3.0 Tesla. The data acquisition system accommodates up to 32 independent receive channels in various increments, and multiple independent coil elements per channel during a single acquisition series. The system uses a combination of time-varying magnetic fields (gradients) and RF transmissions to obtain information regarding the density and position of elements exhibiting magnetic resonance. The RF technology of the Discovery MR750w system integrates an RF transmit architecture designed to improve the overall image uniformity. This technology, called Multi-drive, optimizes RF transmit by adjusting the amplitude and phase of the RF output depending on the anatomy being scanned. In order to support Multi-Drive, the RF Transmit (Tx) chain is changed from

MR750 and both Tx lines are divided into 2 lines with Dual output Exciter, Dual output RF amp, Dual Transmit/Receive Switch (DTRSW), dual UPM and a 70cm-wide patient bore RF body coil.

The system can image in the sagittal, coronal, axial, oblique and double oblique planes, using various pulse sequences and reconstruction algorithms. The Discovery MR750w 3.0T is designed to conform to NEMA DICOM standards (Digital Imaging and Communications in Medicine).

Intended Use: The Discovery MR750w 3.0T is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used. The images produced by the Discovery MR750w 3.0T reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Technology: The Discovery MR750w 3.0T employs the same fundamental scientific technology as its predicate devices of Discovery MR750 and Optima MR450w. Refer to Section 12 for details of the Technical Comparison Table and the Application/Feature Comparison Chart.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

As stated in the FDA document "Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" the following parameters have been measured and documented through testing to NEMA, IEC or ISO standards as referenced throughout this submission and listed in Section 9:

Performance:

- Signal-to-noise ratio (SNR)
- Geometric distortion
- Image uniformity
- Slice thickness
- Spatial resolution

Safety:

- Static field strength
- Acoustic noise
- dB/dt
- RF heating (SAR)
- Biocompatibility

The tests outlined above have been executed with acceptable results. Refer to Section 15, 18 of this submission for the above performance and safety testing results.

The Discovery MR750w 3.0T has been designed to comply with applicable IEC standards as reference to Section 9, 17.

The device has been tested by a Nationally Recognized Testing Laboratory and certified to conform to applicable IEC, UL and CSA standards prior to commercialization of the system.

Numerical simulations were conducted to demonstrate the safety of the Multi-Drive RF transmit system.

The following quality assurance measures were applied to the development of the system as reference to Section 11, 16, 18:

- Risk Analysis and control
- Requirements Reviews
- Design Reviews
- Design Verification
- Performance and Safety testing (Verification)

Summary of Clinical Tests:

Clinical images and clinical results summary demonstrate that the Discovery MR750w 3.0T maintains the same imaging performance results as the predicate systems of Discovery MR750, Optima MR450w. Refer to Section 20 for details of the studies performed.

Conclusion: GE Healthcare considers the Discovery MR750w 3.0T to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

SUPPLEMENTAL #1
February 25, 2016
406 pm

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Toru Shimizu
Regulatory Affairs Specialist
GE Healthcare Japan Corporation
7-127, Asahigaoka 4-Chrome
Hino-Shi, Tokyo, 191-8503
JAPAN

SEP 30 2011

Re: K103327
Trade/Device Name: Discovery MR750w 3.0T System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LNI and MOS
Dated: September 2, 2011
Received: September 7, 2011

Dear Mr. Shimizu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

SUPPLEMENTAL #1
K103327
February 25, 2016
406 pm

510(k) Number (if known): K103327

Device Name: Discovery MR750w 3.0T

Indications for Use:

The Discovery MR750w 3.0T is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used. The images produced by the Discovery MR750w 3.0T reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k)_____

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ATTACHMENT 4A-2
MEDICAL DIRECTOR CV
iMRI

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L. Madison Michael II, M.D., F.A.C.S

Semmes-Murphey Neurologic and Spine Institute
The University of Tennessee Health Sciences Center • Department of Neurosurgery
6325 Humphreys Boulevard • Memphis, TN 38120 • (901) 522-7700
Home: 2941 Robin Road • Memphis, TN 38111 • (901) 458-8011 • mmichael@semmes-murphey.com

Education:

B.S., University of the South, Sewanee, TN
September 1988 – May 1992

M.D., University of Tennessee Health Sciences Center, Memphis, TN
August 1994 – May 1998

Postdoctoral Training:

Internship and Residency

Surgical Internship
University of Tennessee Health Sciences Center, Memphis, TN
Department of General Surgery
June 23, 1998 – June 30, 1999

Resident in Neurosurgery
University of Tennessee Health Sciences Center, Memphis, Memphis, TN
Department of Neurosurgery
July 1, 1999 – June 30, 2004
Special interest in Skull Base Tumors, Complex Spinal Surgery

Clinical Fellowship

North Bristol NHS Trust
Frenchay Hospital, Frenchay, England
Department of Neurosurgery
July 1, 2004 – June 30, 2005
International fellowship in Skull Base Tumors, Complex Spine Surgery

Licensure and Certification:

2005 Tennessee Medical License
2005 American Board of Neurological Surgery, Candidate Member
2007 Mississippi Medical License
2009 American Board of Neurosurgery Diplomate
2010 Fellow, American College of Surgery

Academic Appointments:

2003 Lecturer in Neuroanatomy, University of Tennessee Medical School, Memphis,

Tennessee
2004 Clinical Lecturer, North Bristol NHS Medical School, England
2005 Assistant Professor, University of Tennessee Department of Neurosurgery, Memphis, Tennessee
2005 Attending Neurosurgeon, Semmes-Murphey Neurologic and Spine Clinic, Memphis, Tennessee
2005 Attending Neurosurgeon, Veterans Administration Hospital, Memphis, Tennessee
2006 Academic Mentor, Medical Ethics Course, University of the South, Sewanee, Tennessee
2007 Faculty, Molecular Neurosurgery Research Program, Memphis, Tennessee
2008 Attending Neurosurgeon, LeBonheur Children's Hospital, Memphis, Tennessee
2009 Director of Cranial Base Surgery, Methodist Neuroscience Institute
2009 Director of Neurosurgical Research, Methodist Neuroscience Institute
2009 Medical Director, Methodist Neuroscience Institute
2009 Executive Director, Memphis Regional Brain Tumor Center

Community Service:

1989-1992 Sewanee Volunteer Fire Department, Sewanee, Tennessee
1990-1992 Big Brother Program, Sewanee, Tennessee
2007-Present Rotary Club International, Member
2007 Guest Speaker, Student Leadership Conference, Sewanee, Tennessee
2007-Present Volunteer Faculty, Church Health Center, Memphis, Tennessee
2008-Present Team neurosurgeon, University of Memphis Athletics Department
2008-Present Team neurosurgeon, Rhodes College Athletics Department
2008-Present Team neurosurgeon, Memphis Grizzlies Basketball Team

Hospital Appointments:

2005 Methodist University Hospital, Memphis, Tennessee
2005 The Regional Medical Center, Memphis, Tennessee
2005 Baptist Memorial Hospital, Memphis, Tennessee
2005 The Veterans Administration Hospital
2008 LeBonheur Children's Hospital

Professional Committees:

1996-1998 Medical Student Executive Committee Member
2003 Resident Delegate, Council of State Neurosurgeons
2005-2007 Semmes-Murphey Clinic Peer Review Committee
2005 Methodist University Hospital H*Works OR Task Force
2006 Methodist University Hospital Intensive Care Unit Committee
2006 Scientific Committee, Fifth Annual International Neuro-Oncology Update, Memphis, Tennessee
2006-Present Moderator, Memphis Regional Brain Tumor Conference, Memphis, Tennessee
2006-2007 Methodist University Neuroscience Institute Executive Council, Member

2007-Present	Chair, Methodist University Hospital Neurosurgical Intensive Care Unit Committee
2007	Methodist University Hospital Operating Room Committee
2007	Moderator, Memphis Regional Brain Tumor Conference, Memphis, Tennessee
2007	Moderator, Southern Neurosurgical Society Meeting, Sea Island, Georgia
2007-Present	Member, Semmes-Murphey Clinic Ambulatory Surgery Center Committee
2007-2009	Member, Semmes-Murphey Clinic Quality Improvement Committee
2007-Present	Member, Alpha Omega Alpha Selection Committee
2009-Present	Chair, Semmes-Murphey Clinic Quality Improvement Committee
2009	Assistant Residency Program Director, University of Tennessee Department of Neurosurgery
2009	Site Director, UTHSC Neurosurgery Residency Training Program, Methodist University Hospital location
2010	Assistant Secretary, Board of Governors, Semmes-Murphey Neurologic and Spine Center
2010	Member, Methodist Hospital Credentialing Committee
2010	Advisor, Central Nervous System Cancers, National Comprehensive Cancer Network

Professional Societies:

2005-Present	American Association of Neurological Surgeons, Member
2005-Present	Congress of Neurological Surgeons, Member
2005-Present	American Medical Association, Member
2005-Present	North American Skull Base Society, Member
2005-Present	Tennessee Neurosurgical Society, Member
2005-Present	Memphis and Shelby County Medical Society, Member
2006-Present	American College of Surgeons, Provisional Member
2009-Present	Society of NeuroOncology, Active Member

Course Instructor:

2003-2004	Minimal Access Spinal Technology, Memphis, Tennessee Course involving the use of minimally invasive spinal procedures (Metrx, Sextant).
2003-2008	North American Skull Base Society Residency Workshop, Memphis, Tennessee, Neurosurgical and Otolaryngology resident workshop with emphasis on skull base anatomy/approaches.
2007	Neurosurgical Workshop, Middle Fossa Approach, Neurosurgical Department, National Almenara Hospital, Lima, Peru.
2008-Present	University of Tennessee Skull Base Resident Workshop, Memphis, Tennessee
2008-2009	DLIF instructor, Medtronic Corporation, Memphis, Tennessee.
2008-2009	TLIF instructor, Medtronic Corporation, Memphis, Tennessee.
2010	North American Skull Base Society Residency Workshop, New Orleans, Louisiana, Neurosurgical and Otolaryngology resident workshop with emphasis on skull base anatomy/approaches.

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Awards:

1988-1992	Snowden Academic Scholarship, Sewanee, Tennessee
1988-1992	Bell Academic Scholarship, Sewanee, Tennessee
1989-1992	Red Ribbon Leadership Society, Sewanee, Tennessee
1989-1992	Highlanders Society, Sewanee, Tennessee
1990-1992	Order of the Gownsman Academic Society, Sewanee, Tennessee
1992	Order of the Silver Spoon, Sewanee, Tennessee
1997	93rd percentile on National Medical Board Examination
1998	Alpha Omega Alpha Honor Society
1998	Imhotep Leadership Society
1998	Graduated High Honors from University of Tennessee Medical School
1999	Passed Neurosurgery Boards Part I as PGY-2 (NS-1)
2002	Receiver of the R. L. DeSaussure Award for Neurosurgical Research
2004	Chief Resident of Neurosurgical Service, University of Tennessee Department of Neurosurgery
2010	Matthew Wood Neurosurgical Teaching Award, University of Tennessee Department of Neurosurgery

Clinical Studies:

1. Cervical Arthoplasty using the SpinalMotion Kineflex C Cervical Artificial Disc. (CLOSED)
2. Memphis Regional Brain Tumor Center, Clinical Protocol MHIRB # 2006-032, A Phase I/II Trial of Maximal Resection, Local Radiation Boost with Concomitant Temozolomide, Followed by External Radiation Therapy with Concomitant Temozolomide for the Treatment of Newly Diagnosed Glioblastoma Multiforme. (CLOSED)
3. Memphis Regional Brain Tumor Center, Clinical Protocol, A Phase I/II Trial of Maximal Resection, Radiation Therapy Delivered Via the GliaSite® Delivery System with Concomitant Temozolomide Followed by Temozolomide for the Treatment of Newly Diagnosed Glioblastoma Multiforme. (CLOSED)
4. Memphis Regional Brain Tumor Center, Clinical Protocol, A Phase II Study of Gliadel, Concomitant Temozolomide and Radiation, Followed by metronomic therapy with Temozolomide for newly diagnosed malignant high grade glioma. (CLOSED)
5. Molecular Neurosurgery Research Program, Genomic profiling of central nervous system tumors. (CLOSED)
6. Molecular Neurosurgery Research Program, Genomic profiling of pathological disc material. (CLOSED)
7. Assessment of Nerve Health after Lumbar Decompression Surgery Using Intraoperative Evoked EMG. (CLOSED)
8. Fusion rates between INFUSE Bone Graft/PEEK Interbody Spacer/Anterior Cervical Plate and Allograft/Anterior Cervical Plate.
9. Memphis Regional Brain Tumor Center, Clinical Protocol MHIRB # 2007-050, A Phase II, Multicenter, Exploratory Study, Evaluating the

Treatment Effect of Surgery Plus Gliadel Wafer in Patients with Metastatic Brain Cancer. (CLOSED)

10. Memphis Regional Brain Tumor Center, Clinical Protocol MHIRB # 2007-036, Treatment Satisfaction Survey for Brain Tumor Patients and Their Caregivers. (CLOSED)

11. Memphis Regional Brain Tumor Center, Clinical Protocol MHIRB # 2008-038, Cilengitide for subjects with newly diagnosed glioblastoma multiforme and methylated MGMT gene promoter - a multicenter, open-label, controlled phase III study, testing cilengitide in combination with standard treatment (temozolomide with concomitant radiation therapy, followed by temozolomide maintenance therapy) versus standard treatment alone". (CENTRIC) .

12. Memphis Regional Brain Tumor Center, Clinical Protocol MHIRB # 2008-034, BIBW 2992 with or without daily temozolomide in the treatment of patients with recurrent malignant glioma.

13. Memphis Regional Brain Tumor Center, Clinical Protocol MHIRB # 2007-048, Survey of brain tumor patients about use of the internet for medical information and decision making. (CLOSED)

Presentations:

1. Von Hippel-Lindau Disease, Grand Rounds, Department of Neurosurgery, Barrow Neurological Institute, Phoenix, Arizona, 1997.
2. Post-Traumatic Seizures, Trauma Grand Rounds, Department of Surgery, University of Tennessee at Memphis, Memphis, Tennessee 2000.
3. Acute Spinal Cord Injury in Athletes, Trauma Grand Rounds, Department of Surgery, University of Tennessee at Memphis, Memphis, Tennessee 2000.
4. Ankylosing Spondylitis, Grand Rounds, Department of Neurosurgery, University of Tennessee at Memphis, Memphis, Tennessee 2000.
5. Maxillofacial and Scalp Injury in Neurotrauma Patients, Trauma Grand Rounds, Department of Surgery, University of Tennessee at Memphis, Memphis, Tennessee 2001.
6. Acute Spinal Cord Injury, Trauma Grand Rounds, Department of Surgery, University of Tennessee at Memphis, Memphis, Tennessee 2001.
7. Nonvestibular Schwannomas of the Brain, Society of University Neurosurgeons Meeting, Portland, Oregon 2001.
8. Nonvestibular Schwannomas of the Brain, Society of University Neurosurgeons Meeting, Southern Neurosurgical Society, Savannah, Georgia 2002.
9. The Treatment of Advanced Sinonasal Malignancies with Pre-Operative Intra-Arterial Cisplatin and Concurrent Radiation, Tennessee Neurosurgical Society, Nashville, Tennessee 2004.

10. The Treatment of Advanced Sinonasal Malignancies with Pre-Operative Intra-Arterial Cisplatin and Concurrent Radiation, Southern Neurosurgical Society, Orlando, Florida, 2003.
11. Skull Base Approaches, University of Tennessee Skull Base Symposium, Memphis, Tennessee, 2003.
12. Sinonasal Malignancies: Current Management Options, Neurosciences Grand Rounds, Frenchay Hospital, North Bristol NHS Trust, Frenchay, England, 2004.
13. Anticoagulation in Neurosurgery, Neurosurgery Grand Rounds, Frenchay Hospital, North Bristol NHS Trust, Frenchay, England, 2005.
14. Lymphocytic Hypophysitis (with Rick Nelson, FRCS), Seventh Clinicopathological English Conference on Pituitary Disease, The Royal College of Physicians, London, England, 2005.
15. Neurosurgical Emergencies, Department of Internal Medicine Grand Rounds, Memphis, Tennessee, 2005.
16. Somatosensory Pathways, Department of Neurosurgery Grand Rounds, Memphis, Tennessee, 2005.
17. Neurosurgery in the United Kingdom, Methodist Neuroscience Institute Grand Rounds, Memphis, Tennessee, 2005.
18. British Medicine, Clinical Update in Medicine, Beaver Creek, Colorado, 2006.
19. Balloon Kyphoplasty for Pathological Vertebral Fractures, Methodist University Tumor Board, Memphis, Tennessee, 2006.
20. Brain Tumors, Memphis Regional Brain Tumor Conference, Memphis, Tennessee, 2006.
21. Subarachnoid Hemorrhage, Neurosurgery Education Symposium, Methodist University Hospital, Memphis, Tennessee, 2006.
22. Cranial Base Surgery – The Future, Tennessee Neurosurgical Society, Chattanooga, Tennessee, 2006.
23. Cranial Base Surgery – The Past, Present, and Future, Fifth Annual International Neuro-Oncology Update, Memphis, Tennessee, 2006
24. Cerebellopontine Angle Tumors, University of Tennessee Department of Neurosurgery Grand Rounds, Memphis, Tennessee, 2006.
25. Current Management of Sinonasal Malignancies, 60th anniversary of the Neurosurgical Department of the National Almenara Hospital, Lima, Peru, 2007.
26. Middle Fossa Approach, 60th anniversary of the Neurosurgical Department of the National Almenara Hospital, Lima, Peru, 2007.
27. Neurosurgery and the Emergency Room Physician: What I need to know, Department of Internal Medicine Grand Rounds, Memphis, Tennessee, 2007.
28. The Far Lateral Approach to the Cranial Base – Indications, Results, and Myths, Chattanooga, Tennessee, 2007.

29. The Far Lateral Approach to the Cranial Base, North American Skull Base Course for Residents, 2007.
30. The Future of Methodist University Hospital, Methodist Hospital, 2007.
31. Brain Tumors, University of Tennessee Department of Internal Medicine, Grand Rounds, 2007.
32. Acoustic Neuromas, Grand Rounds, University of Tennessee Department of Neurosurgery Grand Rounds, Memphis, Tennessee, 2007.
33. Facial Pain, Semmes-Murphey Clinic Public Seminar, Memphis, Tennessee, 2008.
34. Thoracolumbar Trauma, Grand Rounds, University of Tennessee Department of Neurosurgery Grand Rounds, Memphis, Tennessee, 2008.
35. Minimally Invasive Spinal Surgery, Grand Rounds, University of Tennessee Department of Neurosurgery Grand Rounds, Memphis, Tennessee, 2008.
36. Anterolateral Corridor Approaches, University of Tennessee Department of Neurosurgery Resident Workshop, Memphis, Tennessee, 2008.
37. The Extended Unilateral Maxillotomy – The University of Tennessee Experience, Tennessee Neurosurgical Society, Nashville, Tennessee, 2008.
38. Nonvestibular Schwannomas, University of Tennessee Department of Neurosurgery Grand Rounds, Memphis, Tennessee, 2009.
39. Neurosurgical Emergencies, Department of Internal Medicine Grand Rounds, Memphis, Tennessee, 2009.
40. Pituitary Adenomas, Semmes-Murphey Clinic Public Seminar, Memphis, Tennessee, 2008.
41. A Prospective Evaluation and Literature Review of Levetiracetam Use In Patients with Brain Tumors and Seizures, Allen K. Sills, L. Madison Michael II, Justin Usery, Christopher Finch, 2009 Joint Meeting of the Society for Neuro-Oncology and the AANS/CNS Section on Tumors, New Orleans, Louisiana, 2009.
42. Radiation Therapy for Pituitary Adenomas, Hamilton Eye Institute Neuro-Ophthalmology Update, Memphis, Tennessee, 2009.
43. Occipitocervical Fusion Techniques, University of Tennessee Department of Neurosurgery Spinal Seminar, Memphis, Tennessee, 2009.
44. Craniofacial Approach for Removal of Esthesioneuroblastoma, 95th Annual Clinical Congress of American College of Surgeons, Chicago, IL, 2009.
45. The Evolution of Cranial Base Surgery, Methodist Cancer Institute, Memphis, Tennessee, 2009.
46. The Classification of Brain Tumors, Department of Internal Medicine Grand Rounds, Memphis, Tennessee, 2010.
47. Far Lateral Approach, North American Skull Base Society Residency Workshop, New Orleans, Louisiana, 2010.

Original Reports:

1. L. Madison Michael II, Anthony Whitworth, Claudio A. Feler. Spina Bifida Occulta as a Contraindication for Percutaneous Spinal Cord Stimulation, Journal of Neuromodulation 2002; 5(1): 38-40.
2. Julius Fernandez, L. Madison Michael II, Claudio A. Feler. Sacral Tip Granuloma following Spinal Cord Stimulator Implantation: Case Report, Journal of Neuromodulation 2003; 6(4) 225-228.
3. L. Madison Michael II, Jon H. Robertson. Glomus Jugulare Tumors: Historical Overview of the Management of Disease, Neurosurgical Focus 2004; 17(2):1-5.
4. L. Madison Michael II, Jeffrey A. Sorenson, Sandeep Samant, Jon H. Robertson. The Treatment of Advanced Sinonasal Malignancies with Pre-Operative Intra-Arterial Cisplatin and Concurrent Radiation, Journal of Neuro-Oncology, 2005; 72(1): 67-75.
5. L. Madison Michael II, Tim Moss, Hugh B. Coakham. Malignant Transformation of Posterior Fossa Epidermoid Cyst, British Journal of Neurosurgery, 2005.
6. Christopher Duntsch, Akbar Sal, Terreia Jones, L. Madison Michael II, John Winestone. Delivery of Temozolomide to the tumor bed via biodegradable gel matrices in a novel model of intracranial glioma with resection, Journal of Neuro-Oncology, 2009.
7. Cyrus Nozad, L. Madison Michael II, D. Betty Lew, Christie F. Michael. Non-allergic rhinitis: A case report and review. Clinical and Molecular Allergy 2010, 8:1.
8. Justin Usery, L. Madison Michael II, Allen Sills, Christopher Finch. A Prospective Evaluation and Literature Review of Levetiracetam Use in Patients with Brain Tumors and Seizures, Journal of Neuro-Oncology, 2010.
9. L. Madison Michael II, Shirin Mazumder, Michael Gelfand. Case Study: Differential Diagnosis of a Patient with Rhomboencephalitis, Infectious Diseases in Clinical Practice, 2010.

Book Chapters:

1. L. Madison Michael II, Wayne Hamm, Jon H. Robertson. Surgical Treatment of Glomus Jugulare Tumors, Chapter in Neurosurgical Operative Atlas: NeuroOncology, Badie, B, Ed. Thieme Publishers, New York, NY 2005.
2. L. Madison Michael II, Jon H. Robertson. Jugular Foramen Tumors, Chapter in Posterior Fossa, Nanda, A, Ed. Thieme Publisher, New York, NY 2008.

Posters:

1. L. Madison Michael II, Kevin T. Foley, Rick A. Boop. Current Management Strategy with Embolization, Resection, and Reconstruction for Aneurysmal

Bone Cysts of the Pediatric Spine, Pediatric Section AANS Meeting, Phoenix, Arizona, 2002.

2. Robert Laster, L. Madison Michael II. Cranial Nerve Lesions, American College of Radiology Annual Meeting, 2004.
3. Winston Ally, April Hurdle, L. Madison Michael II, Allen Sills, Carli Nesheiwat, Chris Finch. Use of hypertonic saline in surgical patients with brain tumors to treat cerebral edema, Society of Critical Care Medicine Annual Meeting, Miami Beach, Florida, 2010.

Press:

1. Innovative thinking leads MLH Neurosurgeon to find creative use for surgical equipment, Methodist LeBonheur Healthcare One Vision Newsletter, August 2007.
2. Methodist University Hospital Neurosurgeon's Research Efforts Hopefully Will Improve Patient Outcomes One Day, Methodist LeBonheur Healthcare One Vision Newsletter, October 2007.
3. Craniofacial Approach for Esthesioneuroblastoma, Channel 5 Healthcast, 2009.
4. Awake Craniotomy, Channel 5 Healthcast, 2009.
5. Removal of a giant skull base tumor in an Iraqi patient, Channel 5 Healthcast, 2009.
6. Removal of a Colloid Cyst in famous opera singer, Channel 5 News, 2009.
7. Physician profile, Memphis Medical News, 2010.

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ATTACHMENT 4B
RADIATION THERAPY
CRITERIA

SUPPLEMENTAL #1
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Project-Specific Review Criteria: Megavoltage Radiation Therapy Services

1. **Utilization Standards for MRT Units.**
   a. **Linear Accelerators not dedicated to performing SRT and/or SBRT procedures.**
      i. **Full capacity of a Linear Accelerator MRT unit is 8,736 procedures, developed from the following formula: 3.5 treatments per hour, times 48 hours (6 days of operation, 8 hours per day, or 5 days of operation, 9.6 hours per day), times 52 weeks.**
      ii. **Linear Accelerator Minimum Capacity: 6,000 procedures per Linear Accelerator MRT Unit annually, except as otherwise noted herein.**
      iii. **Linear Accelerator Optimal Capacity: 7,688 procedures per Linear Accelerator MRT Unit annually, based on 12% average downtime per MRT units during normal business hours annually.**
      iv. **An applicant proposing a new Linear Accelerator should project a minimum of at least 6000 MRT procedures in the first year of service, building to a minimum of 7,688 procedures per year by the third year of service and for every year thereafter.**

Methodist based projections for the Linear Accelerator (LINAC) equipment on historical volumes and forecasted volumes are assumed to be 2% annually through Year 2. Projections meet the minimum requirements. See Tables 1 for the projections.

TABLE 1
LINAC PROJECTIONS

	2013	2014	2015		Year 1 2019	Year 2 2020
Methodist University	2	2	2		3	3
West Cancer Center	1	1	1		2	2
# of Linear Accelerators	3	3	3*		5	5
Procedures / Volumes						
Methodist University	11,742	13,442	15,323		17,887	18,245
West Cancer Center	9,869	11,297	12,878		15,033	15,333
Total	21,611	24,739	28,201		32,920	33,578
Procedures / Volumes per Unit						
Methodist University	5,871	6,721	7,662		5,962	6,082
West Cancer Center	4,934	5,649	6,439		7,516	7,667
Total	7,204	8,246	9,400		6,584	6,716
Note: Added approved Linear Accelerator CN1311-043A in December 2015						

   b. **For Linear Accelerators dedicated to performing only SRT procedures, full capacity is 500 annual procedures.**
   Not Applicable

   c. **For Linear Accelerators dedicated to performing only SRT procedures, full capacity is 850 annual procedures.**
   Not Applicable

   d. **An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for Linear**

Accelerators develop. An applicant must demonstrate that the proposed Linear Accelerator offers a unique and necessary technology for the provision of health care services in the proposed Service Area.
Not Applicable

e. **Proton Beam MRT Units. As of the date of the approval and adoption of these Standards and Criteria, insufficient data are available to enable detailed utilization standard to be developed for Proton Beam MRT Units.**
Not Applicable

2. **Need Standards for MRT Units.**

a. **For Linear Accelerators not dedicated solely to performing SRT and/SBRT procedures, need for a new Linear Accelerator in a proposed Service Area shall be demonstrated if the average annual number of Linear Accelerator procedures performed by existing Linear Accelerators in the proposed Service Area exceeds 6,000.**

The service area is described in detail in #3. Radiation Therapy is primarily an outpatient service and is therefore defined separately from the larger project. The primary service area for LINAC services includes Shelby, Fayette and Tipton counties in Tennessee, Crittenden County, Arkansas, and DeSoto County, Mississippi.

The combined average utilization of existing LINAC units in the primary service area is 5,385 in 2014 for all providers based on the Medical Equipment Registry data. Yet, St. Jude Children's Research Hospital is an internationally recognized pediatric hospital dedicated to research and treatment for children with cancer and other catastrophic diseases. St. Jude is caring for a unique population of patients. Excluding St. Jude's volumes and equipment from the market calculation, the average for LINAC volumes per unit is 6,079 in 2014 which is above the 6,000 threshold.

The volumes from the larger project's secondary Tennessee and Mississippi service area are noted below for informational purpose. There was no Arkansas data available. See Tables 2 and 3 for LINAC market utilization.

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TABLE 2
METHODIST LINAC PRIMARY SERVICE AREA
LINAC EQUIPMENT AND UTILIZATION, 2012-2014

Facility Type	Facility	2012		2013		2014	
		Procs	# of Units	Procs	# of Units	Procs	# of Units
HOSP	Methodist Healthcare	23,756	3	21,611	3	24,739	3
HOSP	Baptist Memorial Hospital-Memphis	11,052	2	10,111	2	10,590	2
ASTC	Baptist Memorial Hospital-Tipton/Germantown	7,610	1	6.963	1	4,647	1
HOSP	St. Francis Hospital – Park	6,795	2	7,480	2	6,332	2
HOSP	St. Jude Children's Research Hospital	4,605	2	3,756	2	4,524	2
HOSP	Baptist Memorial Hospital – DeSoto	10,152	1	8,393	1	8,399	1
Total Procedures		63,970	11	51,358	11	59,231	11
Average Procedures per Unit		5,815		4,669		5,385	
Total Procedures without St. Jude		59,365	9	47,602	9	54,707	9
Average Procedures per Unit without St. Jude		6,596		5,289		6,079	

Source: 2012-14 TN HSDA - State Equipment Registry; and 2013-2015 MS DOH - State Health Plan and MS Hospital Report
Note: Primary Service Area includes Shelby County, TN, DeSoto County, MS and Crittenden County, AR.

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TABLE 3
METHODIST UNIVERSITY SECONDARY TN AND MS SERVICE AREA
LINAC EQUIPMENT AND UTILIZATION, 2012-2014

Facility Type	Facility	2012		2013		2014	
		Procs	# of Units	Procs	# of Units	Procs	# of Units
RAD	Dyersburg Radiation Oncology Center	4,663	1	4,362	1	3,501	1
RAD	Baptist Memorial Hospital-Memphis	4,675	1	4,936	1	3,225	1
HOSP	Jackson-Madison County General Hospital	14,985	3	13,195	3	-	-
HRAD	Kirkland Cancer Center (formerly Jackson-Madison equipment)	-	-	-	-	14,175	3
Free-standing Clinic	Bethesda Cancer Center (Clarksdale, MS)	2,477	1	2,412	1	n/a	n/a
Total Procedures		26,800	6	24,905	6	20,910	5
Average Procedures per Unit		4,467		4,151		4,180	

Source: 2012-14 TN HSDA - State Equipment Registry; and 2013-2015 MS DOH - State Health Plan and MS Hospital Report
Note: There is no radiation therapy noted in Lauderdale, Hardeman or Haywood counties in TN or Tunica, Panola, Tate or Marshall counties in MS. There were no Arkansas data available.

b. **For Linear Accelerators dedicated to performing only SRT, need in a proposed Service Area shall be demonstrated if the average annual number of MRT Procedures performed by existing Linear Accelerators dedicated to performing only SRT procedures in a proposed Service Area exceeds 300, based on a full capacity of 500 procedures.**
Not Applicable

c. **For Linear Accelerators dedicated to performing only SRT/SBRT, need in a proposed Service Area shall be demonstrated if the average annual number of MRT Procedures performed by existing Linear Accelerators dedicated to performing only SRT/SBRT procedures in a proposed Service Area exceeds 510, based on a full capacity of 850 procedures.**
Not Applicable

d. **Need for a new Proton Beam MRT Unit: Due to the high cost and extensive service areas that are anticipated to be required for these MRT Units, an applicant proposing a new Proton Beam MRT Unit shall provide information regarding the utilization and service areas of existing or planned Proton Beam MRT Units' utilization and services areas (including those that have received a CON), if they provide MRT services in the proposed Service Area and if that data are available, and the impact its application if granted, would have on those other Proton Beam MRT Units.**
Not Applicable

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3. **Access to MRT Units.**

   a. **An MRT unit should be located at a site that allows reasonable access for residents of the proposed Service Area.**

   The proposed LINAC will supplement the Methodist units already operating on the Methodist University campus. More than 90% of the patients currently seeking Methodist LINAC services (including Methodist University Hospital and West Cancer Center in Germantown) originate from the designated service area. The designated primary service area includes Shelby, Tipton and Fayette counties in Tennessee, DeSoto County, Mississippi, and Crittenden County, Arkansas. The unit will be located in a site that is accessible and convenient for patients. See Table 4 below for detailed volumes.

TABLE 4
2014 METHODIST LINAC PROCEDURES BY COUNTY

Service Area	Procedures	% of Total
Shelby, TN	18,789	76%
Desoto, MS	1,705	7%
Tipton, TN	908	4%
Fayette, TN	791	3%
Crittenden, AR	515	2%
Subtotal	22,708	92%
Other MS Counties	1,038	4%
Other TN Counties	417	2%
Other AR Counties	408	2%
Out-of-area	168	1%
Total	24,739	100%
Source: 2014 TN HSDA - State Equipment Registry		

   b. **An applicant for any proposed new Linear Accelerator should document that the proposed location of the Linear Accelerator is within a 45 minute drive time of the majority of the proposed Service Area's population.**

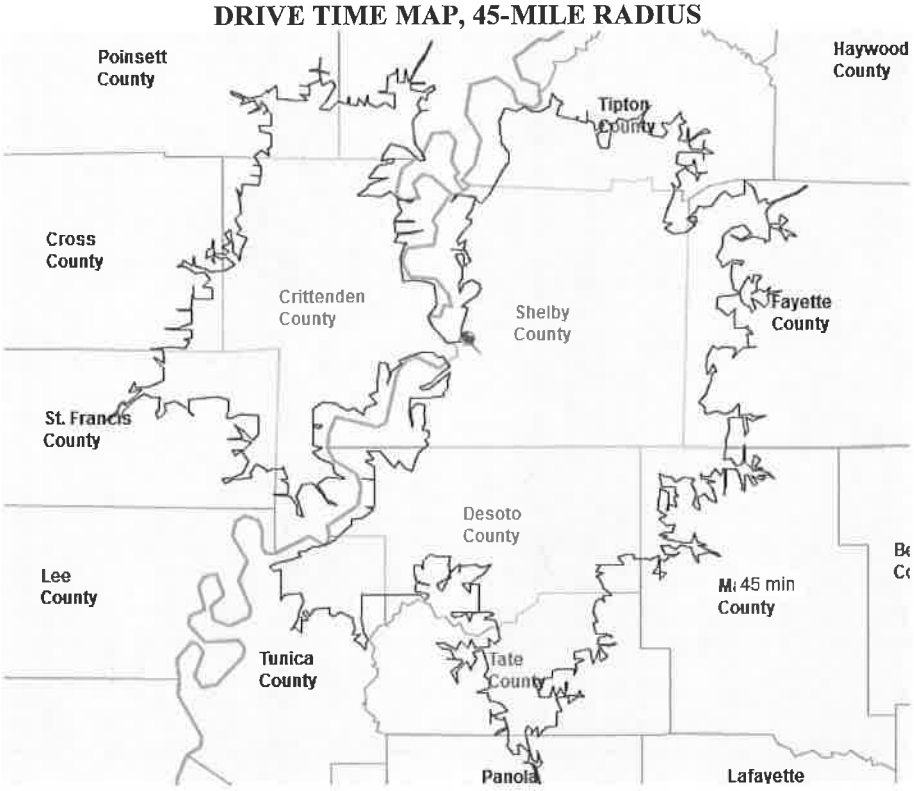
   As noted in the application, the project primary service area includes Shelby County, TN, DeSoto County, MS and Crittenden County, AR. The primary project service will be the service area for this outpatient-dominant equipment. Based on the 2014 Medical Equipment Registry, 82% of the Methodist linear accelerator volumes are from this three-county primary service area.

   The majority (75%) of the population in the Methodist service area is in Shelby County. See Table 5 below for the 2015 population analysis by county. Also, please see the drive time map in Figure 1. The 45-minute drive time radius for the Methodist LINAC services at Methodist University Hospital and the West Cancer Center covers all of Shelby County and the majority of DeSoto and Crittenden counties which accounts for more than 90% of the defined service area - the majority of the population.

TABLE 5
POPULATION BY COUNTY, 2015
METHODIST SERVICE AREA

Service Area	Population	% of Total
Shelby, TN	946,637	75%
DeSoto, MS	168,989	13%
Tipton, TN	59,918	5%
Crittenden, AR	48,531	4%
Fayette, TN	34,845	3%
Total	1,258,920	100%
Source: Truven Healthcare Analytics- Market Expert		

FIGURE 1
DRIVE TIME MAP, 45-MILE RADIUS



c. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRT units that service the non-Tennessee counties and the impact on MRT unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).

The only existing MRT unit in the designated primary service area that is located outside of Tennessee is in DeSoto County, Mississippi. As noted in Table 2 above, the LINAC unit is performing 8,399 in 2014 which is well above (almost 140%) the

minimum threshold of 6,000 procedures per unit. The unit is located at the Baptist Memorial Hospital-DeSoto.

There is a LINAC located at the Bethesda Cancer Center in Coahoma County in Mississippi which is in the secondary service area for the larger project, yet is not the primary service area for LINAC services. The unit in Coahoma is performing approximately 2,400 procedures per year in 2012-2013 – the 2014 volumes were not available.

4. **Economic Efficiencies. All applicants for any proposed new MRT Unit should document that lower costs technology application have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.**

   Alternate services and technologies were investigated. However, there was no lower cost alternative that delivers the accuracy and reliability of the selected LINAC. The machine pinpoints the cancerous cells with real-time imaging and allows providers to precisely target tumors while minimizing the amount of healthy cells exposed to radiation. The speed and localization of the real-time imaging offers more patient comfort and less chance the patient will move during the treatments. The equipment is optimized for both radiotherapy and radiosurgery and can treat cancers almost anywhere in the body, including lung, breast, abdomen and head and neck cancers.

5. **Separate Inventories for Linear Accelerators and for other MRT Units. A separate inventory shall be maintained by the HSDA for Linear Accelerators, for Proton Beam Therapy MRT Units, and if data are available, for Linear Accelerators dedicated to SRT and/or SBRT procedures and other types of MRT Units.**

   Methodist assures the HSDA that all data requested to maintain the Equipment Registry will be submitted within the expected time frame.

6. **Patient Safety and Quality of Care. The applicant shall provide evidence that any proposed MRT Unit is safe and effective for its proposed use.**

   a. **The United States Food and Drug Administration (FDA) must certify the proposed MRT Unit for clinical use.**

      See Attachment 4B-1 FDA certification that was filed with original application.

   b. **The applicant should demonstrate that the proposed MRT Units shall be housed in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.**

      The architect consulted on this project confirms that the physical environment will conform to all applicable federal standards, manufacturer's specifications and licensing agencies' requirements. See Attachment 8B for the architect letter.

   c. **The applicant should demonstrate how emergencies within the MRT Unit facility will be managed in conformity with accepted medical practice.**

The unit will be on the Methodist University Hospital campus. There are clinical technicians and emergency personnel on the premises trained in basic life support when the patient is being scanned. In the event of cardiac or respiratory arrest, trained clinical personnel will initiate basic life support while the patient is being emergently removed from the scan room, and then taken to be treated by appropriate physicians and clinicians.

d. **The applicant should establish protocols that assure that all MRT Procedures performed are medically necessary and will not unnecessarily duplicate other services.**

There are established standard protocols in place for Methodist to ensure all LINAC procedures are medically necessary and will not unnecessarily duplicate other services. All LINAC procedures are required to have a physician's written order that defines the medical necessity. All orders will be reviewed to ensure that there is no unnecessary duplication of services. Methodist has a dedicated team of nurses that precertify all LINAC procedures through the various third party payers. The rigorous precert process ensures medical necessity and assures that the patient does not receive duplicative procedures. See Attachment 4C for the System Policy outlining the guidelines for a physician order for all diagnostic services.

e. **An applicant proposing to acquire any MRT Unit shall demonstrate that it meets the staffing and quality assurance requirements of the American Society of Therapeutic Radiation and Oncology (ASTRO) , the American College of Radiology (ACR). The American College of Radiation Oncology (ACRO) or a similar accrediting authority such as the National Cancer Institute (CNI). Additionally, all applicants shall commit to obtain accreditation from ASTRO, ACR or a comparable accreditation authority for MRT Services within two years following instigation of the operation of the proposed MRT Unit.**

Methodist University Hospital is fully accredited by the American College of Radiology (ACR). Methodist meets the staffing and quality assurance requirements.

f. **All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.**

The need for a transfer agreement is not applicable; the equipment will be located on the Methodist University Hospital campus.

The physician medical director is an active member of the medical staff. See Attachment 4B-2 for current medical director's CV.

g. **All applicants should provide evidence of any onsite simulation and treatment planning services to support the volumes they project and any impact such services may have on volumes and treatment times.**

There is a dedicated CT simulator to support the LINAC services at Methodist University. The CT simulator will support projected volumes. The CT simulator has sufficient capacity to support the volumes and cause no delay in treatment times.

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7. **The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.**

   Methodist assures the HSDA that all data requested to maintain the Equipment Registry will be submitted within the expected time frame.

8. **In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:**

   a. **Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;**
   Not applicable

   b. **Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or**
   Not applicable

   c. **Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.**

      Methodist is certified for both Medicare and TennCare/Medicaid and participates in both programs. Methodist contracts with all of the TennCare plans offered in the service area and with Medicaid in adjoining States. All Methodist hospitals treat TennCare participants under the system's TennCare contracts.

      In comparison to other large counties across the State, Shelby County is the home to a disparate number of low-income families seeking coverage from the state's Medicaid program. Methodist is one of the largest health care providers of TennCare in the State and is committed to these patients as reflected in the projections for this proposal.

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ATTACHMENT 4B-1
FDA CERTIFICATION
RADIATION THERAPY

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K051932

510(k) SUMMARY

Date of preparation of summary:
4th July 2005

Submitted by:
Elekta Limited
Linac House, Fleming Way
Crawley, West Sussex
RH20 9RR
United Kingdom

Contact name, (application correspondent):
Peter Stegagno, Director, Regulatory Affairs & Quality Assurance
4775 Peachtree Industrial Boulevard, Building 300, Suite 300
Norcross, Georgia, 30092
USA

Email: peter.stegagno@elekta.com
Telephone: (770) 300 9725 x2548 Fax: (770) 448 6338

Trade Name:..... Elekta Synergy®, Elekta Synergy® S, and XVI R3.5

Common Name: Medical Linear Accelerator (with Patient Imaging)

Classification Name: Medical Linear Accelerator Accessory 90 IYE

Predicate Device: Elekta Synergy® System (K032996)

Product Description:
This Premarket Notification Special 510(k) describes modifications to the Elekta Synergy® System; a combination of the specially prepared Elekta medical linear accelerator, Elekta Synergy® Platform, with the XVI on-board kV imaging accessory. The primary reasons for the modifications to this product are to provide:

- Hardware & software support for increased patient throughput
- Easier selection of parameters & provision of clinical presets to improve efficiency
- Improved image quality and image management
- Improved tools for device set-up and image processing
- Improved connectivity with other systems through DICOM

Intended Use Statement:
This is unchanged from the predicate device and is defined as;
"The Elekta Synergy®, Elekta Synergy® S, and XVI R3.5
are intended to be used for radiation therapy treatment of malignant neoplastic diseases, as determined by a licensed medical practitioner."

Summary of Technological Characteristics:
The Elekta Synergy® and Elekta Synergy® S comprise a standard Elekta medical linear accelerator, modified to accept the fitting of a kV imaging system (XVI R3.5), with a common MV and kV isocentre and orthogonal beam paths, all as previously cleared under Control Number K032996.

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There has been no change made to the underlying technological characteristics of the product.

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

AUG 1 2 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Elekta Limited
% Mr. Peter Stegagno
Director, Regulatory Affairs
& Quality Assurance
Elekta, Inc.
4775 Peachtree Industrial Boulevard
Building 300, Suite 300
NORCROSS GA 30092

Re: K051932
Trade/Device Name: Elekta Synergy®, Elekta Synergy® S and XVI R3.5
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 8, 2005
Received: July 13, 2005

Dear Mr. Stegagno:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K051932

Device Name ..... Elekta Synergy®, Elekta Synergy® S, and XVI R3.5

Indication for Use: The Elekta Synergy®, Elekta Synergy® S, and XVI R3.5 are intended to be used for radiation therapy treatment of malignant neoplastic diseases, as determined by a licensed physician.

Prescription Use - YES AND/OR Over-The-Counter Use - NO
(Per 21 CFR 801.109 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Clayman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051932

Elekta Limited, Fleming Way, Crawley, West Sussex, RH10 9RR UK +44 1293 544422 Fax: +44 1293 654321

ATTACHMENT 4B-2
MEDICAL DIRECTOR CV
RADIATION THERAPY

SUPPLEMENTAL #1

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Matthew T. Ballo, M.D.

Curriculum Vitae

West Cancer Center, 7945 Wolf River Blvd• Germantown, TN 38138
Office phone: 901-683-0055 • E-Mail: mballo@westclinic.com

Methodist University Hospital, Department of Radiation Oncology
1265 Union Ave• Memphis TN 38104
Office Phone: 901-516-7367

Present Title and Affiliations

Academic Appointment

Professor and Chairman, Department of Radiation Oncology, The University of Tennessee Health Science Center, Memphis, TN

Administrative Appointments

Medical Director, Radiation Oncology, The West Clinic Radiation Oncology Group, Memphis, TN
Director, Radiation Oncology, The University of Tennessee West Cancer Center, Memphis, TN

Education

Degree-Granting Education

Oberlin College, Oberlin, OH, BA, 7/1987 to 6/1991, Biochemistry
Case Western Reserve University School of Medicine, Cleveland, OH, MD, 7/1991 to 6/1995, Medicine

Postgraduate Training

Clinical Internship, Mt. Sinai Medical Center, Cleveland, OH, Richard Ach, M.D., 7/1995–7/1996
Clinical Residency, The University of Texas MD Anderson Cancer Center, Houston, TX, Alan Pollack, M.D., 7/1996–7/2000

Credentials

Board Certification

American Board of Radiology, Radiation Oncology, 47202. Granted: 5/2000, Recertified: 4/2010.

Licensures (Active)

Tennessee Medical License, TN, 50791, 5/31/17
Mississippi Medical License, MS, 23819, 5/13/15
Ohio Medical License, OH, 35071913B, 7/1/2017
Texas Medical Board, TX, L0014, 2/28/2016

Academic Experience

Assistant Professor, Department of Radiation Oncology, Division of Radiation Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, 7/2000–8/2005
Adjunct Assistant Professor –SHS, Radiation Therapy, Department of Radiation Oncology, Division of Radiation Oncology, The University of Texas MD Anderson Cancer Center School of Health Sciences, Houston, TX, 9/2003–present

Associate Professor, Department of Radiation Oncology, Division of Radiation Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, 9/2005–8/2011
Professor, Department of Radiation Oncology, Division of Radiation Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, 9/2011–12/2013
Professor and Chairman, Department of Radiation Oncology, The University of Tennessee Health Science Center, Memphis, TN, 1/2014

Administrative Experience

Deputy Residency Director, Department of Radiation Oncology, Division of Radiation Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, 2000–2006
Clinical Medical Director, Department of Radiation Oncology, Division of Radiation Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, 2006–2008
Associate Medical Director, Regional Care Centers, The University of Texas MD Anderson Cancer Center, Houston, TX, 2009–2011
Service Chief - Radiation Oncology Outreach Program, Department of Radiation Oncology, Division of Radiation Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, 2011–2013
Medical Director - Radiation Oncology, The West Clinic Radiation Oncology Group, Memphis, TN, 2014 - Present
Director - Radiation Oncology, The University of Tennessee West Cancer Center, Memphis, TN, 2014 - Present

Other Appointments and Responsibilities

Local and National Committee Activities

Member, American College of Radiology (ACR) Committee on Residency Training in Radiation Oncology (Commission on Education), American College of Radiology, Houston, TX, 2003–2004
Member, Radiation Therapy Oncology Group (RTOG) Image Guided Radiotherapy Committee, 2006–2007
Member, American Society for Therapeutic Radiology and Oncology Education Committee of the Education Council, 2006–2009
Member, American Society for Therapeutic Radiology and Oncology (ASTRO) Government Relations NIH Subcommittee of the Government Relations Council, 2006–2011
Committee Member, American College of Surgeons Oncology Group (ASCOG), 2006–2006
Member, CHRISTUS St. John's Hospital Cancer Committee, Nassau Bay, TX, 2007–2013
Member, Medical Executive Committee, CHRISTUS St. John's Hospital, Nassau Bay, TX, 2012–2013

Institutional Committee Activities

Member, Radiation Oncology Training Committee, 1999–2000
Member, Clinical Computing Advisory Group (CCAG), 2001
Member, Institutional Review Board Sub-Committee, 2002

Member, Electronic Chart Committee, 2002–2008
Selection Committee Member, Geneva and James Briscoe Physician Assistant Award for Excellence, Houston, TX, 2003
Member, Physics Residency Training Program Committee, 2003–2005
Representative, UT M. D. Anderson Cancer Center Department of Radiation Oncology Faculty Senate, 2003–2006
Participant, UT M.D. Anderson Cancer Center Department of Orthopedic Oncology in the Division of Surgery for Chair Search, 2005
Board Member, Board of Directors to M. D. Anderson Physicians Network, 2008–2010
Member, Regional Care Center Accelerated Partial Breast Irradiation Working Group, 2009–2013
Member, Regional Care Center Research Working Group, 2009–2013

Honors and Awards

Alpha Omega Alpha, Honor Medical Society, 1995
Ivan E. Shalit prize for Excellence in Patient Care, 1995
Anderson Associates Travel Grant Award, 1998
First Prize Gilbert H. Fletcher Award, Gilbert H. Fletcher Society, 1998
First Prize Gilbert H. Fletcher Award, Gilbert H. Fletcher Society, 1999
Excellence in Cancer Patient Education Award, Cancer Patient Education Network, 2011

Publications/Presentations

Peer-Reviewed Original Research Articles

1. **Ballo MT**, Zagars GK, Pisters P, Pollack A. The role of radiation therapy in the management of dermatofibrosarcoma protuberans. Int J Radiat Oncol Biol Phys 1998;40(4):823-7.
2. **Ballo MT**, Garden AS, El-Naggar AK, Gillenwater AM, Morrison WH, Goepfert H, Ang KK. Radiation therapy for early stage (T1-T2) sarcomatoid carcinoma of true vocal cords: outcomes and patterns of failure. Laryngoscope 1998;108(5):760-3.
3. **Ballo MT**, Zagars GK, Pollack A. Radiation therapy in the management of desmoid tumors. Int J Radiat Oncol Biol Phys 1998;42(5):1007-14.
4. **Ballo MT**, Zagars GK, Pollack A, Pisters PW, Pollack RA. Desmoid tumor: prognostic factors and outcome after surgery, radiation therapy, or combined surgery and radiation therapy. J Clin Oncol 1999;17(1):158-67.
5. **Ballo MT**, Strom EA, Prost H, Singletary SE, Theriault RL, Buchholz TA, McNeese MD. Local-regional control of recurrent breast carcinoma after mastectomy: does hyperfractionated accelerated radiotherapy improve local control? Int J Radiat Oncol Biol Phys 1999;44(1):105-12.
6. Cormier JN, Patel SR, Herzog CE, **Ballo MT**, Burgess MA, Feig BW, Hunt KK, Raney RB, Zagars GK, Benjamin RS, Pisters PW. Concurrent ifosfamide-based chemotherapy and irradiation. Analysis of treatment-related toxicity in 43 patients with sarcoma. Cancer 2001;92(6):1550-5.
7. Callister MD, **Ballo MT**, Pisters PW, Patel SR, Feig BW, Pollock RE, Benjamin RS, Zagars GK. Epithelioid sarcoma: results of conservative surgery and radiotherapy. Int J Radiat Oncol Biol Phys 2001;51(2):384-91.
8. **Ballo MT**, Zagars GK, Pisters PW, Feig BW, Patel SR, von Eschenbach AC. Spermatic cord sarcoma: outcome, patterns of failure and management. J Urol 2001;166(4):1306-10.
9. Crane CH, Janjan NA, Evans DB, Wolff RA, **Ballo MT**, Milas L, Mason K, Charnsangavej C, Pisters PW, Lee JE, Lenzi R, Vauthey JN, Wong A, Phan T, Nguyen Q, Abbruzzese JL. Toxicity and

efficacy of concurrent gemcitabine and radiotherapy for locally advanced pancreatic cancer. Int J Pancreatol 2001;29(1):9-18.
10. Porter GA, Cantor SB, Ahmad SA, Lenert JT, **Ballo MT**, Hunt KK, Feig BW, Patel SR, Benjamin RS, Pollock RE, Pisters PW. Cost-effectiveness of staging computed tomography of the chest in patients with T2 soft tissue sarcomas. Cancer 2002;94(1):197-204.
11. Ahmad SA, Patel SR, **Ballo MT**, Baker TP, Yasko AW, Wang X, Feig BW, Hunt KK, Lin PP, Weber KL, Chen LL, Zagars GK, Pollock RE, Benjamin RS, Pisters PW. Extraosseous osteosarcoma: response to treatment and long-term outcome. J Clin Oncol 2002;20(2):521-7.
12. Janjan N, Crane C, Delclos M, **Ballo M**. Brachytherapy for locally recurrent soft-tissue sarcoma. Am J Clin Oncol 2002;25(1):9-15.
13. **Ballo MT**, Strom EA, Zagars GK, Bedikian AY, Prieto VG, Mansfield PF, Lee JE, Gershenwald JE, Ross MI. Adjuvant irradiation for axillary metastases from malignant melanoma. Int J Radiat Oncol Biol Phys 2002;52(4):964-72.
14. Crane CH, Abbruzzese JL, Evans DB, Wolff RA, **Ballo MT**, Delclos M, Milas L, Mason K, Charnsangavej C, Pisters PW, Lee JE, Lenzi R, Vauthey JN, Wong AB, Phan T, Nguyen Q, Janjan NA. Is the therapeutic index better with gemcitabine-based chemoradiation than with 5-fluorouracil-based chemoradiation in locally advanced pancreatic cancer? Int J Radiat Oncol Biol Phys 2002;52(5):1293-302.
15. Little DJ, **Ballo MT**, Zagars GK, Pisters PW, Patel SR, El-Naggar AK, Garden AS, Benjamin RS. Adult rhabdomyosarcoma: outcome following multimodality treatment. Cancer 2002;95(2):377-88.
16. Pisters PW, **Ballo MT**, Patel SR. Preoperative chemoradiation treatment strategies for localized sarcoma. Ann Surg Oncol 2002;9(6):535-42.
17. **Ballo MT**, Gershenwald JE, Zagars GK, Lee JE, Mansfield PF, Strom EA, Bedikian AY, Kim KB, Papadopoulos NE, Prieto VG, Ross MI. Sphincter-sparing local excision and adjuvant radiation for anal-rectal melanoma. J Clin Oncol 2002;20(23):4555-8.
18. Hung A, Crane C, Delclos M, **Ballo M**, Ajani J, Lin E, Feig B, Skibber J, Janjan N. Cisplatin-based combined modality therapy for anal carcinoma: a wider therapeutic index. Cancer 2003;97(5):1195-202.
19. **Ballo MT**, Bonnen MD, Garden AS, Myers JN, Gershenwald JE, Zagars GK, Schechter NR, Morrison WH, Ross MI, Kian Ang K. Adjuvant irradiation for cervical lymph node metastases from melanoma. Cancer 2003;97(7):1789-96.
20. Zagars GK, **Ballo MT**, Pisters PW, Pollock RE, Patel SR, Benjamin RS, Evans HL. Prognostic factors for patients with localized soft-tissue sarcoma treated with conservation surgery and radiation therapy: an analysis of 225 patients. Cancer 2003;97(10):2530-43.
21. Zagars GK, **Ballo MT**. Sequencing radiotherapy for soft tissue sarcoma when re-resection is planned. Int J Radiat Oncol Biol Phys 2003;56(1):21-7.
22. Zagars GK, **Ballo MT**, Pisters PW, Pollock RE, Patel SR, Benjamin RS. Surgical margins and re-resection in the management of patients with soft tissue sarcoma using conservative surgery and radiation therapy. Cancer 2003;97(10):2544-53.
23. Zagars GK, **Ballo MT**, Pisters PW, Pollock RE, Patel SR, Benjamin RS. Preoperative vs. postoperative radiation therapy for soft tissue sarcoma: a retrospective comparative evaluation of disease outcome. Int J Radiat Oncol Biol Phys 2003;56(2):482-8.
24. Zagars GK, **Ballo MT**. Significance of dose in postoperative radiotherapy for soft tissue sarcoma. Int J Radiat Oncol Biol Phys 2003;56(2):473-81.
25. Pisters PW, **Ballo MT**, Fenstermacher MJ, Feig BW, Hunt KK, Raymond KA, Burgess MA, Zagars GK, Pollock RE, Benjamin RS, Patel SR. Phase I trial of preoperative concurrent doxorubicin and radiation therapy, surgical resection, and intraoperative electron-beam radiation therapy for patients with localized retroperitoneal sarcoma. J Clin Oncol 2003;21(16):3092-7.
26. Caudell JJ, **Ballo MT**, Zagars GK, Lewis VO, Weber KL, Lin PP, Marco RA, El-Naggar AK, Benjamin RS, Yasko AW. Radiotherapy in the management of giant cell tumor of bone. Int J Radiat Oncol Biol Phys 2003;57(1):158-65.
27. Zagars GK, **Ballo MT**, Pisters PW, Pollock RE, Patel SR, Benjamin RS. Prognostic factors for disease-specific survival after first relapse of soft-tissue sarcoma: analysis of 402 patients with

disease relapse after initial conservative surgery and radiotherapy. Int J Radiat Oncol Biol Phys 2003;57(3):739-47.
28. Court LE, Dong L, Taylor N, **Ballo M**, Kitamura K, Lee A, O'Daniel J, White R, Cheung R, Kuban D. Inter and Intra-User Variability in CT-Guided Prostate Localization. Int J Radiat Oncol Biol Phys 57(2 Suppl):S332-333, 2003.
29. **Ballo MT**, Zagars GK, Cormier JN, Feig BW, Patel SR, Pisters PW. The Length of Time Between Surgery and Post-Operative Radiotherapy and Local Control for Soft Tissue Sarcoma. Int J Radiat Oncol Biol Phys 2003;57(2 Suppl):S254.
30. Bonnen MD, **Ballo MT**, Myers JN, Garden AS, Diaz EM, Gershenwald JE, Morrison WH, Lee JE, Oswald MJ, Ross MI, Ang KK. Elective radiotherapy provides regional control for patients with cutaneous melanoma of the head and neck. Cancer 2004;100(2):383-9.
31. Zagars GK, **Ballo MT**, Lee AK, Strom SS. Mortality after cure of testicular seminoma. J Clin Oncol 2004;22(4):640-7.
32. Kim KB, Sanguino AM, Hodges C, Papadopoulos NE, Eton O, Camacho LH, Broemeling LD, Johnson MM, **Ballo MT**, Ross MI, Gershenwald JE, Lee JE, Mansfield PF, Prieto VG, Bedikian AY. Biochemotherapy in patients with metastatic anorectal mucosal melanoma. Cancer 2004;100(7):1478-83.
33. **Ballo MT**, Zagars GK, Cormier JN, Hunt KK, Feig BW, Patel SR, Pisters PW. Interval between surgery and radiotherapy: effect on local control of soft tissue sarcoma. Int J Radiat Oncol Biol Phys 2004;58(5):1461-7.
34. Cormier JN, **Ballo MT**. Functional outcome after treatment of lower extremity soft tissue sarcoma: what should we tell our patients? Ann Surg Oncol 2004;11(5):453-4.
35. Court LE, Dong L, Taylor N, **Ballo M**, Kitamura K, Lee AK, O'Daniel J, White RA, Cheung R, Kuban D. Evaluation of a contour-alignment technique for CT-guided prostate radiotherapy: an intra- and interobserver study. Int J Radiat Oncol Biol Phys 2004;59(2):412-8.
36. Pisters PW, Patel SR, Prieto VG, Thall PF, Lewis VO, Feig BW, Hunt KK, Yasko AW, Lin PP, Jacobson MG, Burgess MA, Pollock RE, Zagars GK, Benjamin RS, **Ballo MT**. Phase I trial of preoperative doxorubicin-based concurrent chemoradiation and surgical resection for localized extremity and body wall soft tissue sarcomas. J Clin Oncol 2004;22(16):3375-80.
37. **Ballo MT**, Zagars GK, Gershenwald JE, Lee JE, Mansfield PF, Kim KB, Camacho LH, Hwu P, Ross MI. A critical assessment of adjuvant radiotherapy for inguinal lymph node metastases from melanoma. Ann Surg Oncol 2004;11(12):1079-84.
38. **Ballo MT**, Garden AS, Myers JN, Lee JE, Diaz EM, Sturgis EM, Morrison WH, Gershenwald JE, Ross MI, Weber RS, Ang KK. Melanoma metastatic to cervical lymph nodes: Can radiotherapy replace formal dissection after local excision of nodal disease? Head Neck 2005;27(8):718-21.
39. Vorburger SA, Xing Y, Hunt KK, Lakin GE, Benjamin RS, Feig BW, Pisters PW, **Ballo MT**, Chen L, Trent J, Burgess M, Patel S, Pollock RE, Cormier JN. Angiosarcoma of the breast. Cancer 2005;104(12):2682-8.
40. **Ballo MT**, Ross MI, Cormier JN, Myers JN, Lee JE, Gershenwald JE, Hwu P, Zagars GK. Combined-modality therapy for patients with regional nodal metastases from melanoma. Int J Radiat Oncol Biol Phys 2006;64(1):106-13.
41. Pawlik TM, Ross MI, Prieto VG, **Ballo MT**, Johnson MM, Mansfield PF, Lee JE, Cormier JN, Gershenwald JE. Assessment of the role of sentinel lymph node biopsy for primary cutaneous desmoplastic melanoma. Cancer 2006;106(4):900-6.
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radiotherapy and reconstructive surgery on wound complications after resection of extremity soft-tissue sarcomas. Ann Surg Oncol 2006;13:1209-15.
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63. **Ballo MT**, Postma KE, Washington CM, Buchholz TA, Cox JD. Development of a successful outreach program at M. D. Anderson Cancer Center: a global perspective. J Am Coll Radiol 2008;5:1170-3.
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69. **Ballo MT**, Chronowski GM, Schlembach PJ, Bloom ES, Arzu IY, Kuban DA. Prospective peer review quality assurance for outpatient radiation therapy. Pract Radiat Oncol. 2014;4(5):279-84.
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Invited Articles

1. **Ballo MT**, Ang KK. Radiation therapy for malignant melanoma. Surg Clin North Am 83(2):323-42, 4/2003.
2. **Ballo MT**, Zagars GK. Radiation therapy for soft tissue sarcoma. Surg Oncol Clin N Am 12(2):449-67, vii, 4/2003.
3. **Ballo MT**, Lee AK. Current results of brachytherapy for soft tissue sarcoma. Curr Opin Oncol 15(4):313-8, 7/2003.
4. **Ballo MT**, Ang KK. Radiotherapy for cutaneous malignant melanoma: rationale and indications. Oncology (Williston Park) 18(1):99-107; discussion 107-10, 113-4, 1/2004.

Editorials

1. **Ballo MT**, Pollack A, Zagars GK. Controversies in the Management of Stage I Seminoma. Oncology 1998;12:1217-1221.
2. **Ballo MT**, Pisters PWT. Commentary on: Improving breast cancer quality of care with the use of patient navigators [Am Surg. 2010;76:1043-1046] Breast Disease: A Yearbook Quarterly 2011;22:256-257.
3. **Ballo MT**, Reed VK. Commentary on: Accelerated partial breast irradiation with interstitial implants: risk factors associated with increased local recurrence [Int J Radiat Oncol Biol Phys. 2011;80:1458-1463] Breast Disease: A Yearbook Quarterly 2012;23:85.
4. **Ballo MT**, Reed VK. Commentary on: Psychosocial group intervention for patients with primary breast cancer: a randomized trial [Eur J Cancer. 2011;47:1363-1372]. Breast Diseases: A Year Book Quarterly. 2012;23:230.

Abstracts (last 10 years)

1. **Ballo MT**. Melanoma metastatic to cervical lymph nodes: Can radiotherapy replace formal lymph node dissection after wide local excision? Annual Meeting of the American Society for Therapeutic Radiology and Oncology, Atlanta, GA, 2004.
2. **Ballo MT**. Mortality after apparent cure of patient with soft tissue sarcoma. Annual Meeting of the Connective Tissue, Montreal, Canada, 2004.

3. **Ballo MT**. Complications of Combined Modality Treatment of Primary Lower Extremity Soft Tissue Sarcomas. Connective Tissue Oncology Society 11th Annual Meeting, Boca Raton, FL, 2005.
4. **Ballo MT**. The Periosteal Margin in Soft Tissue Sarcomas. Connective Tissue Oncology Society 11th Annual Meeting, Boca Raton, FL, 2005.
5. **Ballo MT**. Therapeutic Lymphadenectomy Alone Versus Adjuvant Radiotherapy for Regional Nodal Metastases from Melanoma. American Society of Clinical Oncology 44th Annual Meeting, Chicago, IL, 2008.
6. **Ballo MT**. A Peer Review Program for Outpatient Radiotherapy. Annual Meeting of the American Society for Therapeutic Radiology and Oncology, San Diego, CA, 2010.
7. Bolukbasi Y, Selek U, Saglam Y, Kataria A, Unal Z, Alpan VZ, Kirsner S, **Ballo MT**. Breath hold irradiation technique for left sided breast cancer significantly reduces cardiac radiation exposure. Annual Meeting of the European Society for Radiotherapy and Oncology, Barcelona, Spain, 2012.
8. Selek U, Bolukbasi Y, Saglam Y, Alpan V, Kirsner S, **Ballo MT**. Volumetric Arc Therapy Seems More Promising To Spare Organ At Risk In Adjuvant Postoperative Radiotherapy For Pancreas Adenocarcinoma In Comparison To Step And Shoot Intensity Modulated Radiotherapy. Annual Meeting of the American Society for Radiation Oncology, Boston, MA, 2012.

Book Chapters

1. **Ballo MT**. Radiation Therapy for Soft Tissue Sarcoma. In: Atlas of Cancer, 1. Lippincott Williams & Wilkins: Philadelphia, PA, 360-363, 2002.
2. **Ballo MT**, Shadle K, Pollack A. Radiotherapy in the Management of Seminoma. In: Atlas of Genitourinary Oncology, 1. W. B. Saunders Company: Philadelphia, PA, 205-216, 2002.
3. Janjan NA, Delclos ME, **Ballo MT**, Crane CH. Palliative Care. In: Radiation Oncology. Rationale, Technique, Results. 8. Mosby: St. Louis, MO, 954-986, 2003.
4. Janjan NA, **Ballo MT**, Delclos ME, Crane CH. The Anal Region. In: Radiation Oncology. Rationale, Technique, Results. 8. Mosby: St. Louis, MO, 537-556, 2003.
5. Janjan NA, Delclos ME, **Ballo MT**, Crane CH. The Colon and Rectum. In: Radiation Oncology. Rationale, Technique, Results. 8. Mosby: St. Louis, MO, 497-536, 2003.
6. **Ballo MT**, Zagars GK. The Soft Tissue. In: Radiation Oncology. Rationale, Technique, Results, 8. Mosby: St. Louis, MO., 884–911, 2003.
7. **Ballo MT**, Ross MI. Anal Melanoma. In: Clinical Scenarios in Surgical Oncology. Lippincott Williams & Wilkins: Philadelphia, PA, 173-177, 2005.
8. **Ballo MT**, Ang KA. Malignant Melanoma. In: Clinical Radiation Oncology, 2. Elsevier, Churchill Livingstone: Philadelphia, PA, 865-977, 2007.
9. **Ballo MT**. Radiation Therapy for Soft Tissue Sarcoma. In: Atlas of Cancer, 2. Lippincott Williams & Wilkins: Philadelphia, PA, 360-363, 2008.
10. **Ballo MT**, Zagars GK. Soft Tissue Sarcoma. In: Advanced Therapy in Surgical Oncology, 1. BC Decker Inc., Hamilton: Ontario, Canada, 684-691, 2008.
11. McGovern SL, **Ballo MT**. Radiation Oncology in Skin Cancer Treatment. In: Skin Cancer Management, A Practical Approach, 1. Springer: New York, NY, 259-271, 2010.
12. **Ballo MT**, Zagars Gk. The Soft Tissue. In: Radiation Oncology. Rationale, Technique, Results. 8. Mosby: St. Louis, MO, 884-911, 2010.
13. **Ballo, MT**, Ang KK. Malignant Melanoma. In: Clinical Radiation Oncology, 3rd. Ed(s) LL Gunderson & JE Tepper. Elsevier: Philadelphia, 771-782, anticipated 2014.

Research Experience

Protocols (Funded)

Principal Investigator, A pilot phase II study of pre-operative radiation therapy and thalidomide for low grade primary soft tissue sarcoma or preoperative MAID/thalidomide/radiation therapy for high/intermediate grade primary soft tissue sarcoma of the extremity or body wall, RTOG 0330, 2004.

Protocols (Unfunded)

Principal Investigator, Image guided radiotherapy to analyze reproducibility of our lateral decubitus breast boost technique, MDACC 2011-0706, 2011.

Teaching Experience

Organization of Conferences/Symposia (Include chairing session)

Rad Onc 2002, MD Anderson Department of Radiation Oncology, Houston, TX, Chair, 2002
Rad Onc 2004, MD Anderson Department of Radiation Oncology, Houston, TX, Chair, 2004
Texas Radiological Society, Radiation Oncology Section, Houston, TX, Vice Chair, 2013
Texas Radiological Society, Radiation Oncology Section, Houston, TX, Chair, 2014

Member of Editorial Review Board

Guest Editor, Breast Diseases: A Yearbook Quarterly, 2011–present

Journal Reviewer

Reviewer, American Journal of Clinical Oncology, 2014-present
Reviewer, International Journal of Radiation Oncology, Biology, Physics, 2000–present
Reviewer, Cancer, 2002–present
Reviewer, International Journal of Cancer, 2002–present
Reviewer, British Journal of Cancer, 2003–present
Reviewer, Radiotherapy and Oncology, 2003–present
Reviewer, Journal of Clinical Oncology, 2008–present
Reviewer, European Journal of Surgical Oncology, 2010–present
Reviewer, Lancet Oncology, 2011–present
Reviewer, Case Reports in Medicine, 2012–present
Reviewer, Head and Neck, 2008-present

Manuals, Teaching Aids, Other Teaching Publications

Ballo MT. Radiotherapy Review for the National Boards: A Comprehensive Guide for Residents.

Formal Teaching Courses Taught

Lecturer, Malignant Melanoma for Radiation Oncology Residents. Yearly, 2000–2007
Lecturer, Soft Tissue Sarcoma for Radiotherapists. Yearly, 2000–present
Lecturer, Basic Introduction to Radiation Oncology to 4th year medical students rotating on Hematology/Oncology Rotation. 2005–2008
Lecturer, Soft Tissue Sarcoma for Baylor Radiation Oncology Residents. Yearly, 2007–present
Lecturer, Introduction to Radiation Oncology for St John's Nurses, CHRISTUS St. John's. 2012

Presentations at National or International Conferences (Invited)

1. The Role of Radiation in Treatment of Melanoma, Ashville, NC, 2002
2. The Role of Radiation in Treatment of Soft Tissue Sarcoma, Ashville, NC, 2002

3. Novel Forms of Radiation Therapy, Association of Physician Assistants in Oncology, Austin, TX, 2003
4. The Role of Intraoperative Radiotherapy for Recurrent Rectal Cancer, Advances and Controversies in Clinical Oncology, Steamboat Springs, CO, 2003
5. Management of Patients with a Positive Sentinel Lymph Node from Malignant melanoma, Advances and Controversies in Clinical Oncology, Steamboat Springs, CO, 2004
6. Radiotherapy for patient with soft tissue sarcoma: who gets XRT and who needs it?, Advances and Controversies in Clinical Oncology, Park City, UT, 2005
7. Complications of Combined Surgery and Radiation Therapy of Primary Lower Extremity Soft Tissue Sarcomas, Western Orthopedic Association 70th Annual Meeting, Santa Fe, NM, 2006
8. Resection and Brachytherapy for Recurrent Soft Tissue Sarcoma Arising in a Previously Irradiated Field., American Brachytherapy Society Meeting, San Francisco, CA, 2006
9. Treatment of Soft Tissue Sarcomas Abutting Bone, Musculoskeletal Tumor Society Annual Meeting, Key West, FL, 2006
10. An Introduction to Radiation Oncology, Amarillo Cancer Programs Consortium, Amarillo, TX. 2007
11. Education Session on the Management of Patients with Soft Tissue Sarcoma, American Society for Therapeutic Radiology and Oncology, Los Angeles, CA, 2007
12. Education Session on the Management of Patients with Soft Tissue Sarcoma, American Society for Therapeutic Radiology and Oncology, Boston, MA, 2008
13. Discussant for the Plenary Session Abstract Presentation, American Society for Therapeutic Radiology and Oncology, Chicago, IL, 2009

Affiliations/Memberships

National and International

Alpha Omega Alpha Honor Medical Society, Menlo Park CA, Member, 1996-present
American College of Radiation Oncology, Bethesda, MD, Member, 1996–2000
Connective Tissue Oncology Society, Alexandria, VA, Member, 2000–2007
International Society of Intraoperative Radiation Therapy, Houston, TX, Member, 2000–2005
American Society for Therapeutic Radiology and Oncology, Fairfax, VA, Member, 1996–present
American College of Radiology, Reston, VA, Member, 2000–present,
American Society of Clinical Oncologists, Alexandria, VA, Member, 2000–present

Local/State

Gilbert H. Fletcher Society, Houston, TX, Active Member, 2000–present
Texas Radiological Society, Austin, TX, Member, 2000–present
Harris County Medical Society, Houston, TX, Active Member, 2001–present
Texas Medical Association, Austin, TX, Member, 2001–present

SUPPLEMENTAL #1
February 25, 2016
406 pm

ATTACHMENT 4C
PHYSICIAN ORDER POLICY

SUPPLEMENTAL #1

February 25, 2016
4:06 pm

	THIS	REPLACES
INDEX	S-05-051	
REVISED	04/03/06	01/10/06
EFFECTIVE	01/01/01	
PAGE	1 of 2	

SYSTEM POLICY

ORIGINATOR: Administration

SUBJECT: Outpatient Orders for Diagnostic Services

PURPOSE: To establish guidelines under which the medical staff can order outpatient, non-surgical services in a Methodist Healthcare facility.

FUNCTIONS AFFECTED: Patient Access Services (including Scheduling, Patient Registration, Outpatient Care Center), all ancillary service areas, Health Information Management (outpatient record department) and Utilization Review.

POLICY: Methodist Healthcare recognizes that federal legislation placed an affirmative duty on Hospitals and Physicians to document authorization and medical necessity for outpatient diagnostic services. Failure to abide by CMS regulations has serious penalties for providers of healthcare, including the possibility of personal liability for those who do not properly document and code.

All functions affected must work with Medical staff members and referring physicians to ensure that the following guidelines are met prior to procedures being performed:

1. All requests for diagnostic outpatient services (i.e. any test, procedure, treatment or other service) must be accompanied by a **written, signed and dated** Physician order. A Physician or a Nurse Practitioner may submit this signed order. Rubber stamp signatures are not acceptable. In the case of recurrent care outpatient encounters, one order will be valid for 6 months as long as the physician name, treatment regimen and medical necessity documentation remains unchanged.

2. Patients arriving for an outpatient diagnostic service for whom an order has not been sent to Patient Access or the ancillary department prior to the patients' arrival, will be asked to wait or be rescheduled until the order is received by facsimile or other appropriate means.

In order to ensure compliance for our coding and billing functions, this policy will be followed for all payer groups (not just our Medicare patient population).

SUPPLEMENTAL #1

February 25, 2016
4:06 pm

	THIS	REPLACES
INDEX	S-05-051	
REVISED	04/03/06	01/10/06
EFFECTIVE	01/01/01	
PAGE	2 of 2	

APPROVED:

Peggy Troy
COO, Methodist Healthcare

AUTHORIZED:

Gary S. Shorb
CEO, Methodist Healthcare

SUPPLEMENTAL #1
February 25, 2016
406 pm

ATTACHMENT 8A
CORRECTED
PROJECT COST CHART

SUPPLEMENTAL #1
February 25, 2016
406 pm

PROJECT COSTS CHART

A.	Construction and equipment acquired by purchase:		
	1.	Architectural and Engineering Fees	$ 11,200,000
	2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	10,000
	3.	Acquisition of Site	-
	4.	Preparation of Site	6,750,000
	5.	Construction Costs	172,150,000
	6.	Contingency Fund	18,245,000
	7.	Fixed Equipment (Not included in Construction Contract)	-
	8.	Moveable Equipment (List all equipment over $50,000)	50,900,000
	9.	Other (Specify) Technology and Soft Costs	20,700,000
B.	Acquisition by gift, donation, or lease:		
	1.	Facility (inclusive of building and land)	
	2.	Building only	
	3.	Land only	
	4.	Equipment (Specify) _____	
	5.	Other (Specify) _____	
C.	Financing Costs and Fees:		
	1.	Interim Financing	
	2.	Underwriting Costs	
	3.	Reserve for One Year's Debt Service	
	4.	Other (Specify) _____	
D.	Estimated Project Cost (A+B+C)		279,955,000
E.	CON Filing Fee		45,000
F.	Total Estimated Project Cost (D+E)	**TOTAL**	$ 280,000,000

SUPPLEMENTAL #1
February 25, 2016
406 pm

ATTACHMENT 8B
REVISED
ARCHITECT LETTER

SUPPLEMENTAL #1
February 25, 2016
406 pm

Turner

Turner Construction Company
5300 Virginia Way
Brentwood, TN 37027
phone: 615-231-6300
fax: 615-231-6301

January 17, 2016

Methodist University Hospital
Attn: Mr. Richard Kelley
1265 Union Ave
Memphis, TN 38104

RE: MUH Campus Master Plan - Estimate
Methodist University Hospital

To Whom It May Concern:

We have prepared a current cost estimate on the Methodist University Hospital located in Memphis, TN. We have reviewed the program and believe that this representation of the scope for this project based on current market conditions, historical data, and schematic architect's documents at this stage will be sufficient for this project. Turner Construction as the Nation's largest Healthcare builder has completed hundreds of projects similar in scope. We have used this historic cost database as a basic of our estimate. Some Tennessee projects that we have used for comparison are the Cookeville Regional Medical Center new patient tower and Vanderbilt Children's Hospital expansion schedule to start this year. We have also looked at 5 other project that are similar in size and scope that we have completed in the last 5 years across the United States. We have included escalation based on our experience and what the market is forecasting until this project begins. The following is our estimated cost:

Sitework - $4,850,000
Building Demolition – $1,900,000
Building Construction - $172,150,000

The above includes 3% escalation until the project begins construction.

Working with HKS Inc., this facility will be designed and built to 2009 International Building Code plus City of Memphis and Shelby County amendments as well as 2010 AIA Guidelines for Design and Construction of Health Care Facilities.

Should you have any questions or need any clarifications regarding this information above, please feel free to contact me.

Sincerely,

Andy Davis
Project Executive
Turner Construction

CC: Chuck Lane (MUH), Marty Keith (MUH), Dave Rosenbaum (MLH), Tom Briggs (HKS)

SUPPLEMENTAL #1
February 25, 2016
406 pm

ATTACHMENT 10A
REVISED FUNDING LETTER

SUPPLEMENTAL #1
February 25, 2016
406 pm

Methodist
Le Bonheur Healthcare

February 19, 2016

Melanie Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building
502 Deaderick Street, 9th Floor
Nashville, TN 37243

Dear Ms. Hill:

This is to certify that Methodist Le Bonheur Healthcare has adequate financial resources for the Methodist Healthcare – University Hospital Onsite Replacement and Modernization project.

The applicant, Methodist Healthcare–Memphis Hospitals, is a not-for-profit corporation that operates five Shelby County hospitals under a single license. The applicant is a wholly-owned subsidiary of a broader parent organization, Methodist Le Bonheur Healthcare, which is a not-for-profit corporation with ownership and operating interests in multiple other healthcare facilities of several types in West Tennessee and North Mississippi.

The capital cost of the project is estimated at $280,000,000. Cash is held at the corporate level. Methodist Le Bonheur Healthcare has available cash balances to commit to this project. .

Sincerely,

Chris McLean
Executive Vice President and Chief Financial Officer

SUPPLEMENTAL #1
February 25, 2016
406 pm

ATTACHMENT 10B
HISTORICAL DATA CHART
METHODIST UNIVERSITY HOSPITAL

SUPPLEMENTAL #1
February 25, 2016
406 pm

HISTORICAL DATA CHART

Methodist University Hospital

Give information for the last *three (3)* years for which complete data are available for the facility or agency. The fiscal year begins in January (Month).

	Year 2013	Year 2014	Year 2015
A. Utilization Data (Specify unit of measure) Adjusted Patient Days	209,281	203,523	213,747
B. Revenue from Services to Patients		(in thousands)	
1. Inpatient Services	$ 906,782	$ 941,802	$ 1,058,001
2. Outpatient Services	600,674	663,985	674,912
3. Emergency Services	54,019	59,021	90,990
4. Other Operating Revenue	19,545	19,502	45,956
Gross Operating Revenue	**$ 1,581,020**	**$ 1,684,310**	**$ 1,869,858**
C. Deductions from Gross Operating Revenue			
1. Contractual Adjustments	$ 980,117	$ 1,071,820	$ 1,186,601
2. Provision for Charity Care	152,563	156,455	157,759
3. Provisions for Bad Debt	45,997	43,673	45,881
Total Deductions	**$ 1,178,677**	**$ 1,271,948**	**$ 1,390,241**
NET OPERATING REVENUE	**$ 402,343**	**412,362**	**479,617**
Operating Expenses			
1. Salaries and Wages	$ 125,793	$ 123,888	$ 132,746
2. Physician's Salaries and Wages	3,173	3,275	3,430
3. Supplies	113,069	115,234	143,068
4. Taxes	439	468	429
5. Depreciation	14,713	15,703	18,094
6. Rent	403	404	412
7. Interest, other than Capital	0	0	0
8. Management Fees a) Fees to Affiliates	1,265	963	925
b) Fees to Non-Affiliates	0	0	0
9. Other Expenses	138,701	149,461	159,233
Total Operating Expenses	**$ 397,557**	**$ 409,396**	**$ 458,335**
E. Other Revenue (Expenses) – Net	$ 6,739	$ 5,449	$ 6,206
NET OPERATING INCOME (LOSS)	**$ 11,525**	**8,415**	**27,488**
F. Capital Expenditures			
1. Retirement of Principal	$ -	$ -	$ -
2. Interest	2,896	2,555	2,213
Total Capital Expenditures	$ 2,896	$ 2,555	$ 2,213
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	**$ 8,629**	**5,860**	**25,275**

SUPPLEMENTAL #1

February 25, 2016
406 pm

Other Operating Revenue:	Cafeteria
	Drugs
	Telephone rental
	Vending
	Office Rental
	Ground
	Transportation
	Fix Wing
	Grants
	United Way Grants
	Misc. Income
Other Expenses:	Benefits
	Repairs and Maintenance
	Professional Fees
	Contract Services
	Accounting/Auditing Fees
	Legal/Consulting
	Fee
	Advertising
	Dues and Subscriptions
	Education/ Travel
	Utilities
	Insurance
	Food services
	Laundry Services
	Print Shop
	Telephone
	Transcription
	Academic Support
	Contributions
	License/Accredidations Fees
	Postage/Freight
	Procurement Card Exp
Other Revenue/Expenses:	
	Capital Campaign Funding
	Interest Income
	Gain/Loss on Disposal of PPE

SUPPLEMENTAL #1
February 25, 2016
406 pm

ATTACHMENT 13
LETTERS OF SUPPORT

Methodist University Hospital
Transplant Institute

THE UNIVERSITY of TENNESSEE HEALTH SCIENCE CENTER

February 18, 2016

Melanie M. Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson State Office Building, Ninth Floor
502 Deaderick Street
Nashville, TN 37243

Dear Ms. Hill:

I am writing this letter in support of the proposed Methodist University Hospital Certificate of Need application which has been filed with your agency. I am the Program Director of the Methodist University Hospital Transplant Institute and Professor of Surgery at the University of Tennessee Health Science Center in Memphis, TN.

The UT program partnered with Methodist Le Bonheur Healthcare in 2004 and formed the Methodist University Hospital Transplant Institute (MUHTI). More than 1,000 liver transplants and 1,000 kidney transplants have been performed at MUHTI and Le Bonheur Children's Hospital since 2006. MUHTI serves the highest percentage of minority patients in the country and has the only pediatric liver transplant program in the underserved Mid-South (TN, AR, and MS). MUHTI is renowned for the most experience in steroid-free liver transplantation in the world. The Institute ranks among the top 10 liver transplant programs, the top 15 overall transplant programs in the nation, and has performed over 6,000 transplants.

The experience of receiving a transplanted organ is unlike any other patient experience. Patients embark on a lifelong journey with the transplant care team. From pre-transplant testing through the wait for an organ and then to life changing transplant surgery, the Institute serves as a home away from home. As patients return again and again for post-transplant medical, social, psychological and spiritual support, the importance of a comprehensive care center as a home becomes even more critical. This enduring connection to the Transplant Institute makes it imperative that the facility provide integrated inpatient and outpatient service offerings in a single building.

The care we provide our transplant patients is extraordinary, but the facility where those patients receive care is not. Currently, our Institute is spread over several buildings on campus. This causes not only stress on patients and families navigating the many steps in the Transplant process, but also taxes the efficiency of our care model. On behalf of our patients, families, staff and physicians, I ask that you strongly consider the application before you.

Thank you for your consideration on this matter.

Sincerely,

James D. Eason, MD, FACS
Program Director, Chief of Transplantation
Professor of Surgery

1211 Union Avenue • Suite 340 • Memphis, Tennessee 38104 • 901-516-9183 • Toll Free 1-866-805-7710
www.methodisthealth.org/transplant

SUPPLEMENTAL #1
February 25, 2016
406 pm

The University of Tennessee
WEST
Institute for Cancer Research

February 18, 2016

Ms. Melanie M. Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson State Office Building, Ninth Floor
502 Deaderick Street
Nashville, Tennessee 37243

Dear Ms. Hill:

I write to you in support of the proposed Methodist University Hospital Certificate of Need application which has been filed with your agency. As the Executive Director of West Cancer Center, I can attest to historic growth for our organizations, as we continue to expand our services and facilities.

This letter is written with great enthusiasm to ask for your support from the Tennessee Health Services and Development Agency. Collaboration has been the igniting force for our partnership with Methodist Healthcare, as we embarked collectively and steadfastly on a mission to combine the foremost experts in patient care, research and education in order to provide the best possible cancer treatment for patients both here in Memphis and across the United States.

Upon approval of this project we will march forward with continued enhancement of oncology services to our entire community, specifically in the downtown Memphis region where we will care for many underserved and uninsured. No longer will patients have to visit multiple office locations for the often complex interventions needed for their cancer treatment. Much like our East Memphis Campus, they can see their entire team of expert physicians, all in a single visit on the Methodist University Campus. The net result is a collaborative environment that will foster our comprehensive approach to treatment and transform the delivery of oncology care in the Mid-South.

I thank you for your serious consideration this application rightfully deserves.
Sincerely,

Lee S. Schwartzberg, M.D., F.A.C.P.
Executive Director

SUPPLEMENTAL #1
February 25, 2016
406 pm

The University of Tennessee
WEST
Institute for Cancer Research

February 18, 2016

Ms. Melanie M. Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson State Office Building, Ninth Floor
502 Deaderick Street
Nashville, Tennessee 37243

Dear Ms. Hill:

I am writing this letter in support of the proposed Methodist University Hospital Certificate of Need application which has been filed with your agency. As the Chief Executive Officer of the University of Tennessee West Cancer Center, it is with great enthusiasm that we write this support letter to the Tennessee Health Services and Development Agency. West Cancer Center represents over 50 cancer-focused physician providers in Memphis and the Mid-South community.

We are taking steps to assure that all cancer patients – no matter their socioeconomic background – have access to the life-saving resources and exceptional care provided by our world-class physicians and faculty. The approval of this project will allow for this continued enhancement of oncology services to our entire community, specifically in the downtown Memphis region. The project will provide West Cancer Center with the ability to add additional access points to our community members, as well as, provide for growth as we prepare ourselves for the predicted increase in cancer incidence rates over the next 5 – 7 years.

This project, not only prepares us for that well documented need, but also allows us to integrate our services into one site. The delivery of multidisciplinary care within one cancer center is the best way to treat cancer patients in our community. Patients will no longer have to go to many sites to receive care for this terrible disease. The approval of this application is imperative for us to continue our mission and face our fight against cancer for our community and the mid-south region.

Thank you for your consideration of this application which will positively affect the outcomes of many cancer patients and their caregivers for years to come.

Sincerely,

Erich A. Mounce
Chief Executive Officer

SUPPLEMENTAL #1
February 25, 2016
406 pm

The University of Tennessee
WEST
Institute for Cancer Research

February 18, 2016

Ms. Melanie M. Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson State Office Building, Ninth Floor
502 Deaderick Street
Nashville, Tennessee 37243

Dear Ms. Hill:

Please accept my letter of support for the proposed Methodist University Hospital Certificate of Need application recently filed with your agency. As the Department Chair of the Radiation Oncology Division of West Cancer Center, it is with sincere optimism that we write this support letter to the Tennessee Health Services and Development Agency.

All of the major advances in the field of Radiation Oncology have been directed at personalizing the way radiation is delivered. With our proposed West Cancer Center Campus at Methodist University, we will have the opportunity to provide "side-by-side" care for our patients through the ease of collaboration with other faculty members working within the system.

Radiation Oncologists are an integral part of so many of our patient's multi-disciplinary team -- working together with Medical Oncologists and Surgical Oncologists to develop treatment protocols that personalize the care that is prescribed. This only leads to better outcomes for our patients.

Many of the patients we currently treat at Methodist University have so many barriers to care. By providing this "side-by-side" protocol, we can vastly increase the chances for our patient's survival, and ease many burdens on their caregivers.

I sincerely thank you for your consideration of this application which will positively affect the outcomes of many cancer patients and their caregivers.

Respectfully yours,

Matthew Ballo M.D., F.A.C.R.
Department Chair, Radiation Oncology

SUPPLEMENTAL #1
February 25, 2016
406 pm

SEMMES MURPHEY
Leaders in Brain & Spine Care

Neurosurgery
Jon H. Robertson, M.D.
Michael S. Muhlbauer, M.D.
Kevin T. Foley, M.D.
Maurice M. Smith, M.D.
Stephanie L. Einhaus, M.D.
Rodney G. Ollnger, M.D.
Frederick A. Boop, M.D.
Jeffrey M. Sorenson, M.D.
Kenan Arnautovic, M.D., Ph.D.
L. Madison Michael, II, M.D.
Julius Fernandez, M.D.
Adam S. Arthur, M.D., M.P.H.
Jason A. Weaver, M.D.
Daniel A. Holt, M.D., M.P.H.
Todd E. Fountain, M.D.
Paul Klimo, Jr., M.D., M.P.H.
John D. Brophy, M.D.
LaVerne R. Lovell, M.D.
Raul J. Cardenas, M.D.

Pediatric Neurosurgery
Michael S. Muhlbauer, M.D.
Stephanie L. Einhaus, M.D.
Frederick A. Boop, M.D.
Paul Klimo, Jr., M.D., M.P.H.

Endovascular Neurosurgery
Adam S. Arthur, M.D., M.P.H.
S. David Morris, M.D.
Daniel A. Holt, M.D., M.P.H.
Lucas Elijovich, M.D.
Robert E. Laster, M.D.

Stroke & Critical Care Neurology
Lucas Elijovich, M.D.

Neurology
Lance J. Wright, M.D.
Feiyu Chen, M.D., Ph.D.
Lucas Elijovich, M.D.
Vishad Kumar, M.D.
Debashis Biswas, M.D.

Anesthesiology, Pain Management
Samuel C. Polk, M.D.
Autry J. Parker, M.D.

Physical Medicine & Rehabilitation
Manuel F. Carro, M.D.
Samuel C. Polk, M.D.

Neuropsychology
L. Keith Atkins, Ph.D., ABPP-CN
Susan McChesney Atkins, Ph.D., ABPP-CN
Brandon C. Baughman, Ph.D., ABPP-CN

February 18, 2016

Melanie M. Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson State Office Building, Ninth Floor
502 Deaderick Street
Nashville, TN 37243

Dear Ms. Hill:

I am writing this letter in support of the proposed Methodist University Hospital Certificate of Need application, which has been filed with your agency. My name is L. Madison Michael II, MD. I am currently Chief of Neurosurgery at Methodist-University Hospital. In addition, I am Associate Professor and Program Director of the Neurosurgery Residency program here at the University of Tennessee and a member of the Semmes-Murphey Clinic.

Our department delivers the general and subspecialty neurosurgical care for the hospital. Neurological critical care and endovascular services also fall under our control. Because of the academic affiliation of Methodist with the University of Tennessee, we have been able to develop a comprehensive Neuroscience Institute that provides exceptional care, produces original research, and educates the next generation of physicians.

Our efforts at maximizing efficiency have been stifled by the physical layout of the hospital. Utilizing a tower concept, we will be able to consolidate our entire service line in one location. As health-care providers, this is the ideal working space. The results of this effort will improve the services we offer, resulting in streamlined work-flow and improved patient care.

Methodist University Hospital has demonstrated a commitment to excellence and improvement every step of the way. Their support of adding an intraoperative MRI scanner to the campus is a clear example of this. Technological advancements, along with vertical integration of our service line, will change the way we practice neurosurgery and allow us to establish a world-class institute of excellence.

Thank you for your consideration on this matter. We hope to see approval of this project.

Sincerely,

L. Madison Michael II, MD, FAANS, FACS
Associate Professor and Residency Program Director

SUPPLEMENTAL #1
February 25, 2016
406 pm

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF Shelby

NAME OF FACILITY: Methodist University Hospital

I, Jeffrey H. Liebman, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

CEO
Signature/Title

Jeffrey H. Liebman
CEO, Methodist University Hospital
SVP, Methodist Healthcare

Sworn to and subscribed before me, a Notary Public, this the 23 day of FEBRUARY, 2016, witness my hand at office in the County of Shelby, State of Tennessee.

NOTARY PUBLIC

My commission expires September 30, 2017.

DEBRA D SAVAGE
STATE OF TENNESSEE
NOTARY PUBLIC
COUNTY OF SHELBY
MY COMM. EXP. SEPT. 30, 2017

HF-0043

Revised 7/02

SUPPLEMENTAL #2
February 29, 2016
1:16 pm

ORIGINAL

SUPPLEMENTAL-2

Methodist HealthCare Memphis Hospital

CN1602-009

SUPPLEMENTAL #2
February 29, 2016
1:16 pm

TRAUGER & TUKE
ATTORNEYS AT LAW
THE SOUTHERN TURF BUILDING
222 FOURTH AVENUE NORTH
NASHVILLE, TENNESSEE 37219-2117
TELEPHONE (615) 256-8585
TELECOPIER (615) 256-7444

February 29, 2016

VIA HAND DELIVERY

Ms. Melanie Hill
Executive Director
State of Tennessee
Health Services & Development Agency
502 Deaderick Street, 9th Floor
Nashville, TN 37243

RE: Methodist Healthcare-Methodist Hospitals d/b/a
Methodist University Hospital Certificate of Need Application
For Onsite Replacement and Modernization of the Hospital Campus

Dear Ms. Hill,

Enclosed please find a Supplemental Response #2, in triplicate, to be filed on behalf of my client Methodist Healthcare-Methodist Hospitals d/b/a Methodist University Hospital. Please date stamp the additional enclosed copy of the Response and return it to me.

Thank you for your assistance.

Very truly yours,

Byron R. Trauger /kmn

Byron R. Trauger

BRT:kmn

Enclosures

cc: Carol Weidenhoffer (via email)

SUPPLEMENTAL #2
February 29, 2016
1:16 pm

METHODIST HEALTHCARE—MEMPHIS HOSPITALS

SUPPLEMENTAL RESPONSE #2
CN1602-009

ONSITE REPLACEMENT AND MODERNIZATION OF THE METHODIST UNIVERSITY HOSPITAL CAMPUS

MEMPHIS, SHELBY COUNTY

Filed February 2016

SUPPLEMENTAL #2
February 29, 2016
1:16 pm

1. Section C, Need, Item 1 (Project Specific Criteria) and Section C, Need, Item 5 (Service Area Provider Utilization – MRI and Radiation Therapy Services)

Item 1 - The responses to the project specific criteria are noted. With respect to Table 1 in Attachment 4A (MRI) of the supplemental response, it would be helpful to provide an additional table that shows the combined inventory and utilization of the MRI services operating on all campuses under Methodist University Hospital's license.

UTILIZATION OF MRI EQUIPMENT 2012-2014

	2012		2013		2014	
Fixed Equipment	**Proc**	**# of Units**	**Proc**	**# of Units**	**Proc**	**# of Units**
Hospital-Based Equipment (HOSP)						
Le Bonheur Children's Hospital *	5,289	2	5,260	2	5,340	2
Methodist Healthcare - Germantown Hospital	6,557	2	6,892	2	6,904	2
Methodist Healthcare - South Hospital	4,139	1	4,090	1	3,487	1
Methodist Healthcare - North Hospital	6,092	2	6,003	2	6,415	2
Methodist Healthcare - University Hospital	9,803	3	10,524	3	11,130	3
Off-Campus Equipment						
West Clinic, P.C (ASTC/ODC)	1,564	1	1,287	1	1,655	1
Subtotal MRI	**33,444**	**11**	**34,056**	**11**	**34,931**	**11**
Le Bonheur Children's Hospital iMRI	**68**	**1**	**73**	**1**	**92**	**1**
Total MRI including iMRI	**33,512**	**12**	**34,129**	**12**	**35,023**	**12**

Source: Medical Equipment Registry (as of 8/10/2015)

*Note: Le Bonheur Children's Hospital has two standard pediatric MRIs and an iMRI which is used specifically for neurosurgery. Volumes for the iMRI are excluded in top of the chart and shown separately.

The MRI at West Clinic in Germantown is not on a hospital campus but is hospital-based equipment and owned and operated under the Methodist Healthcare-Memphis Hospitals license.

As mentioned previously, Le Bonheur Children's Hospital, part of the Methodist Healthcare-Memphis Hospitals, currently operates an iMRI. See the historical volumes above for this special use equipment at Le Bonheur. An iMRI is a special-use MRI that is used in the operating room. Similar to the Le Bonheur iMRI, this proposal is for an intraoperative magnetic resonance imaging (iMRI) unit for use in the neurosurgery operating room. This equipment will be used to assist neurosurgeons in the resection of brain tumors initially. Without this technology, MRI testing must be done in the hospital's radiology department post-operatively. This delayed imaging could identify the further need for surgery and the patient will have to undergo a subsequent surgery. iMRI is advanced technology in medicine that bridges the specialties of surgery and radiology. With this technology, the precision and success of surgical treatment of epilepsy and brain tumor removal increase.

Item 5 - The tables requested for purposes of providing a summary of the utilization of **MRI and Radiation Therapy providers** is noted. In the interest of consistency with Table 3 in Attachment 4A (MRI) and Table 2/ Table 3 in Attachment 4B (Radiation

Therapy), please revise the table by including a count of the number of units for each provider. An example is shown in the table below.

Provider Summary, Applicant's TN County Service Area
MRI Summary

County	#Units by Provider Type*	2012 Scans	2013 Scans*	2014 Scans*	% Change '12-'14
Shelby (PSA)	HOSP (26 then 27 in 2013-4)	70,173	68,880	69,161	-1.4%
	PO (6)	27,064	26,351	26,897	-0.6%
	RPO (1)	6,538	6,737	6,505	-0.5%
	H-Imaging (3)	3,331	2,688	3,680	10.5%
	ODC (1)	2,214	2,563	2,889	30.5%
	ASTC/ODC (1)	1,564	1,287	1,655	5.8%
Shelby County (PSA)		**110,884**	**108,506**	**110,787**	-0.1%
Shelby County Scans per Unit		**2,918**	**2,782**	**2,841**	
Shelby County w/o HOSP St Jude		**102,147**	**100,201**	**102,410**	0.3%
Shelby County w/o HOSP St Jude Scans per Unit		**3,004**	**2,863**	**2,926**	
TN Counties in SSA ((7)	HOSP-Fixed (5)	15,536	14,639	13,205	-15.0%
	PO (3)	7,626	7,552	8,364	9.7%
	HODC (3)	7,027	6,491	7,090	0.9%
	ODC (1)	6,781	8,835	10,676	57.4%
	HOSP-Mobile (1)	389	292	314	-19.3%
TN Counties (SSA)		**37,359**	**37,809**	**39,649**	**6.1%**
TN Counties Scans per Unit		**2,874**	**2,908**	**3,050**	**6.1%**
TN Counties w/o HOSP Mobile (1 mobile unit)		**36,970**	**37,517**	**39,335**	**6.4%**
TN Counties w/o HOSP Mobile Scans per Unit		**3,081**	**3,126**	**3,278**	**6.4%**

Please note a correction from the previous chart filed for Shelby County 2013 scans per unit to 2,782. There was a typo in the previous chart which this corrects and adds the counts of equipment. The second subtotal for the Tennessee PSA excludes the 4 units at St. Jude.

Provider Summary, Applicant's TN County Service Area
Radiation Therapy/Linear Accelerator Summary

County	#Units by Provider Type*	2012 Scans	2013 Scans*	2014 Scans*	% Change '12-'14
Shelby (PSA)	HOSP (10)	56,360	51,351	54,584	-3.2%
	ASTC (1)	7,610	6,963	4,647	-38.9%
Shelby County (PSA)		**63,970**	**58,314**	**59,231**	**-7.4%**
Shelby County Scans per Unit		**5,815**	**5,301**	**5,385**	**-7.4%**
Shelby County w/o HOSP St Jude		**59,365**	**54,558**	**54,707**	**-7.8%**
Shelby County w/o HOSP St Jude Scans per Unit		**6,596**	**6,062**	**6,079**	**-7.8%**
TN Counties in SSA ((7)	HOSP (3)	14,985	13,195	-	-100.0%
	HRAD (3)	-	-	14,175	n/a
	RAD (2)	9,338	9,298	6,726	-28.0%
TN Counties (SSA)		**24,323**	**22,493**	**20,901**	**-14.1%**
TN Counties Scans per Unit		**4,865**	**4,499**	**4,180**	**-14.1%**

The second subtotal for the Tennessee PSA excludes the 2 units at St. Jude.

**Note:Provider type can be abbreviated using the following legend: H (hospital); HOPD (hospital outpatient department); ODC (outpatient diagnostic center); PO (private medical practice; RPO (radiologist physician office). Please check with Alecia Craighead, Stat III, for assistance with data available from the HSDA Equipment Registry*

2. Section C, Need, Item 6

The table showing the utilization of the hospital's MRI, Radiation Therapy and PET services is noted.

With respect to MRI, it appears that the utilization specific to the 3 MRI units on the applicant's main campus was provided in the table. Please complete the table below showing the historical and projected MRI utilization of Methodist University Hospital's main campus and the combined utilization of the MRI service operating under the hospital's consolidated license.

Service	2013	2014	2015 Preliminary	% Change '13-15'	2016 Projected	Year 1	Year 2
MRI (main University Campus)	10,524	11,130	11,100	5.5%	11,297	11,979	12,159
MRI (satellite locations)	23,605	23,893	23,610	0.0%	n/a	n/a	n/a
MRI (combined University and satellite locations)	34,129	35,023	34,710	1.7%	n/a	n/a	n/a
Source: Tennessee Medical Equipment Registry as of 8/2015 and internal data Note: Satellite locations include Methodist North, Methodist South, Methodist Le Bonheur Germantown, Le Bonheur Children's Hospital and West Cancer Center (off-campus, hospital-based equipment) Also, includes the Le Bonheur iMRI with volumes noted in #1 above and 122 iMRI procedures performed in 2015 as noted in earlier responses.							

Per previous conversation, the projected volumes were calculated for the project-only equipment in 2016 and through Year 1 and Year 2 so are shown as n/a-not applicable.

SUPPLEMENTAL #2
February 29, 2016
1:16 pm

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF Shelby

NAME OF FACILITY: Methodist University Hospital

I, Jeffrey H. Liebman, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Signature/Title CEO

Sworn to and subscribed before me, a Notary Public, this the 29th day of February, 2016, witness my hand at office in the County of Shelby, State of Tennessee.

Martha A. Curry
NOTARY PUBLIC

My commission expires 11/2, 2019.

HF-0043

Revised 7/02

MARTHA A. CURRY
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF SHELBY
MY COMM. EXP. NOV. 02, 2019